UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

þ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2017
OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number **001-37797**

INNOVATE BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**27-3948465**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*

8480 Honeycutt Road, Suite 120
Raleigh, North Carolina 27615
(Address of principal executive offices, including zip code)

(919) 275-1933
(Registrant's telephone number, including area code)

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of each class	Name of each exchange on which registered
Common Stock $0.0001 Par Value	The Nasdaq Stock Market LLC

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT: None

Indicate by check mark if the registrant is a well-known seasoned issuer as defined in Rule 405 of the Securities Act. Yes ☐ No þ

Indicate by check mark if the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes ☐ No þ

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes þ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes þ No ☐

Indicate by check mark if the disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or an amendment to this 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small reporting company. See the definitions of "large accelerated filer," "accelerated filer," "non-accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	þ
(Do not check if smaller reporting company)		Emerging growth company	þ

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No þ

The aggregate value of common stock held by non-affiliates of the registrant as of June 30, 2017, the last business day of the registrant's most recently completed second fiscal quarter, was $3,878,345 (based on the last reported closing sale price on the Nasdaq Capital Market on that date of $4.90 per share).

As of March 12, 2018, the registrant had 25,691,680 shares of common stock, par value $0.0001 per share, issued and outstanding.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). When used in this report, the words "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "expect," "plan," "indicate," "seek," "should," "would" and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. All statements other than statements of historical fact are statements that could be deemed forward-looking statements.

These forward-looking statements are based on our current expectations and beliefs and necessarily involve significant risks and uncertainties that may cause our actual results, performance, prospects and opportunities in the future to differ materially from those expressed or implied by such forward-looking statements. These risks and uncertainties include, among other things, risks related to our limited operating history; our need for substantial additional funding; the lengthy, expensive and uncertain nature of the clinical trial process; results of earlier studies and trials not being predictive of future trial results; our need to attract and retain senior management and key scientific personnel; our reliance on third parties; our ability to manage our growth; potential delays in commencement and completion of clinical studies; our ability to obtain and maintain effective intellectual property protection; and other risks described with these in greater detail in "Risk Factors" of this Annual Report on Form 10-K. These forward-looking statements are made as of the date of this Annual Report on Form 10-K, and we assume no obligation to update or revise them to reflect new events or circumstances except as required by law.

PART I

Item 1. Business.

Merger of Monster Digital, Inc. and Innovate Biopharmaceuticals Inc.

On January 29, 2018, Monster Digital, Inc. ("Monster") and privately held Innovate Biopharmaceuticals Inc. ("Private Innovate") completed a reverse recapitalization in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated July 3, 2017, as amended (the "Merger Agreement"), by and among Monster, Monster Merger Sub, Inc. ("Merger Sub") and Private Innovate, which changed its name in connection with the transaction to IB Pharmaceuticals Inc. ("IB Pharmaceuticals"). Pursuant to the Merger Agreement, Merger Sub merged with and into IB Pharmaceuticals with IB Pharmaceuticals surviving as the wholly owned subsidiary of Monster (the "Merger"). Immediately following the Merger, Monster changed its name to Innovate Biopharmaceuticals, Inc. ("Innovate"). In connection with the closing of the Merger, Innovate's common stock began trading on the Nasdaq Capital Market under the ticker symbol "INNT" on February 1, 2018. Prior to the Merger, Monster was incorporated in Delaware in November 2010 under the name "Monster Digital, Inc."

Except as otherwise noted or where the context otherwise requires, as used in this report, the words "we," "us," "our," the "Company" and "Innovate" refer to Innovate Biopharmaceuticals, Inc. as of and following the closing of the Merger on January 29, 2018 and, where applicable, the business of Private Innovate prior to the Merger. All references to "Monster" refer to Monster Digital, Inc. prior to the closing of the Merger.

Overview

Prior to the Merger, Monster's primary business focus was the design, development and marketing of premium products under the "Monster Digital" brand for use in high-performance consumer electronics, mobile products and computing applications.

After the Merger, we are a clinical-stage biopharmaceutical company developing novel medicines for autoimmune and inflammatory diseases with unmet needs. Our pipeline includes drug candidates for celiac disease, nonalcoholic steatohepatitis (NASH), Crohn's disease (CD) and ulcerative colitis (UC). Our lead program, INN-202 (larazotide acetate or larazotide) is entering Phase 3 registration trials, targeted for the second half of 2018, and has the potential to be the first-to-market therapeutic for celiac disease, an unmet medical need, which affects an estimated 1% of the North American population or approximately 3 million individuals. Celiac patients have no treatment alternative other than a strict lifelong adherence to a gluten-free diet, which is difficult to maintain and can be deficient in key nutrients. Additionally, current FDA labeling standards allow up to 20 parts per million (ppm) of gluten in "gluten-free" labelled foods, which are sufficient to cause celiac symptoms in many patients, including abdominal pain, abdominal cramping, bloating, gas, headaches, ataxia, ''brain fog'' and fatigue. Long-term ramifications of celiac disease include enteropathy associated T-cell lymphoma (EATL), osteoporosis and anemia.

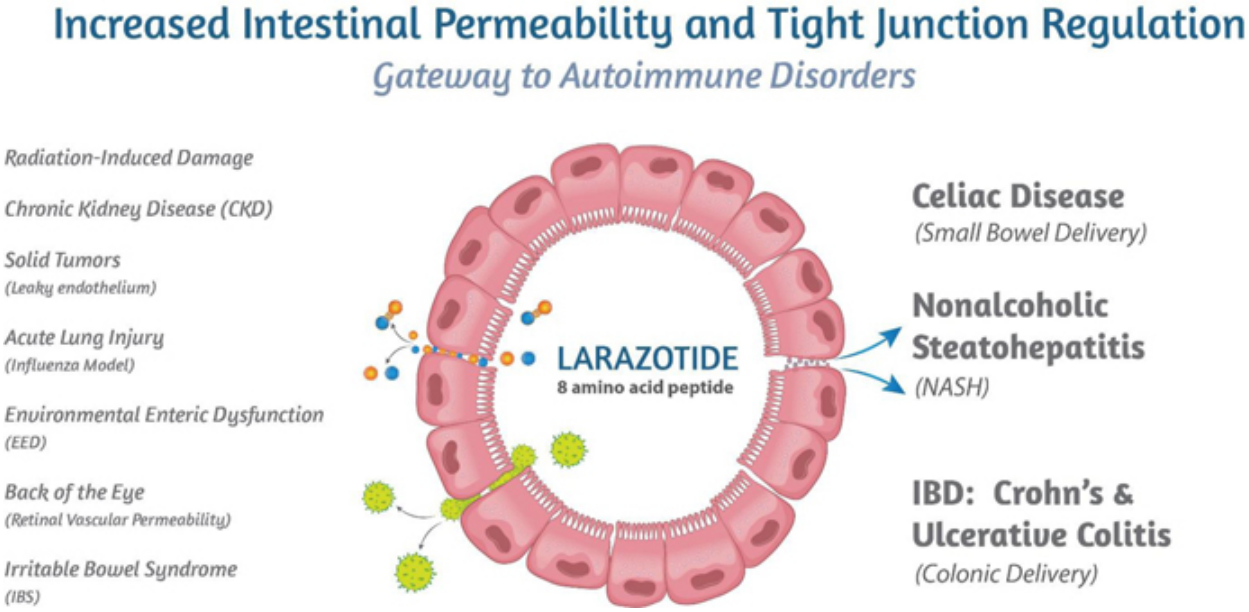

Figure 1: Larazotide's mechanism of action is applicable to multiple diseases.

Larazotide is an 8-amino acid peptide orally administered in a capsule which has been tested in more than 500 celiac patients with statistically significant improvement in celiac symptoms. The FDA has granted larazotide Fast Track Designation for celiac disease. Larazotide's safety profile was similar to placebo primarily because larazotide is not systemically absorbed into the blood circulation. Additionally, larazotide's mechanism of action (MoA) as a tight junction regulator is a new approach to treating autoimmune diseases, such as celiac disease. Pre-clinical studies have shown larazotide causes a reduction in permeability across the intestinal epithelial barrier, making it the only drug candidate known to us which is in clinical trials with this MoA. Increased intestinal permeability underlies several diseases in addition to celiac disease, including NASH, Crohn's disease, ulcerative colitis and irritable bowel syndrome (IBS), among others (Figure 1). We are engaging in multiple research collaborations to expand larazotide's clinical indications with a shorter time to proof-of-concept due to its favorable safety profile.

With the release of the Phase 2b trial data in 342 celiac patients at the 2014 Digestive Disease Week (DDW) conference, larazotide became the first and the only drug for the treatment of celiac disease (published data), which met its primary efficacy endpoint with statistical significance. The Phase 2b data showed statistically significant (p=0.022) reduction in abdominal and non-GI (headache) symptoms as measured by the CeD PRO. After a successful End-of-Phase 2 meeting with the FDA, which confirmed the regulatory path forward, we expect to launch the Phase 3 registration program later this year with topline data expected by 2019.

Larazotide is being investigated as an adjunct to a gluten-free diet for celiac patients who continue to experience symptoms despite adhering to a gluten-free diet. Due to the difficulty of maintaining a gluten-free diet due to lack of easy access to and the higher cost of gluten-free foods, contamination from gluten as well as social pressures, it is estimated that more than half the celiac population experiences multiple, potentially debilitating, symptoms per month. A study from the UK indicates that more than 70% of patients diagnosed with celiac disease consume gluten either intentionally or inadvertently (Hall et al. 2013).

Another indication for which larazotide is currently being developed is NASH. NASH is an unmet need disease affecting approximately 5%-6% of the US adult population. There are currently several drugs in development; however, to our knowledge, none have larazotide's MoA. We are developing a proprietary formulation of larazotide, INN-217, for efficient delivery to the intestine. INN-217 has the potential to reduce the transport of lipopolysaccharide (LPS), which is produced by gram negative bacteria in the gut, from the intestinal lumen to the liver via the portal circulation. Several studies have shown the link between NASH and increased levels of LPS, which translocates across an inflamed, "leaky" epithelial barrier to the liver thus directly damaging liver cells via an inflammatory cascade. INN-217 can potentially decrease the flux of LPS across the leaky epithelial barrier, which is known to play an important role in the pathogenesis of NASH. Since none of the NASH drugs in development currently target intestinal permeability, INN-217 has the potential to affect NASH alone and work synergistically with late stage NASH drugs in development, which are primarily focused on metabolic targets such as farnesoid X receptor (FXR) and acetyl-CoA carboxylase (ACC).

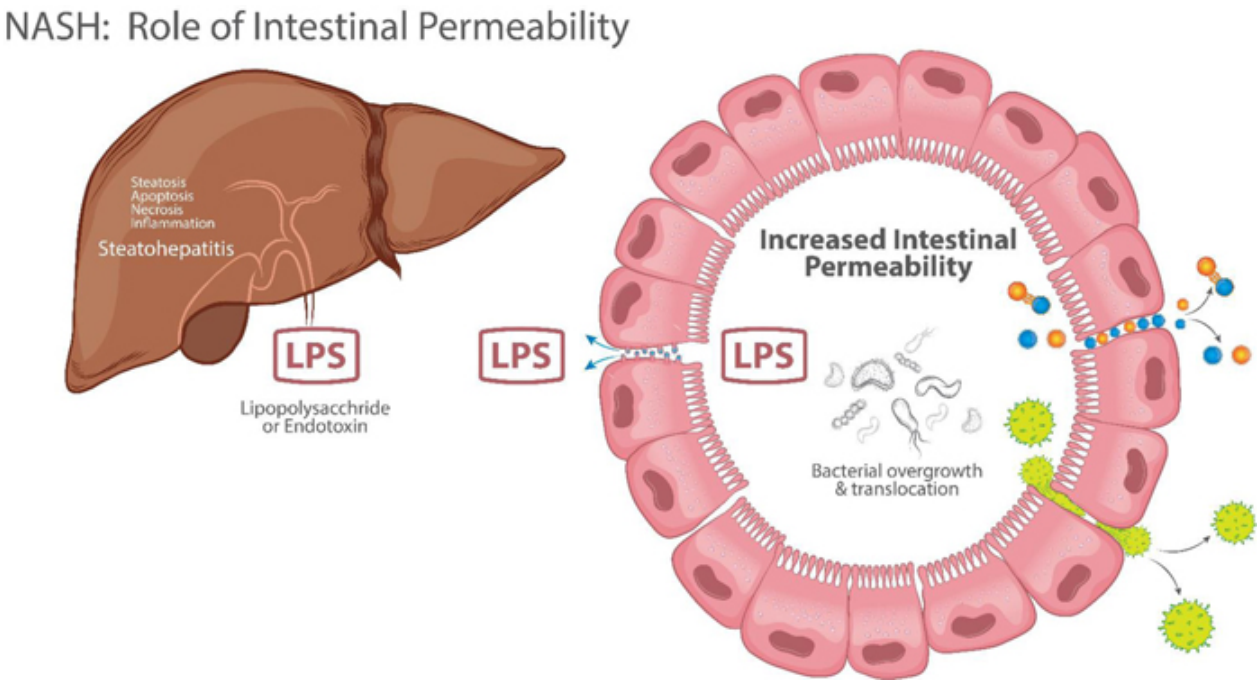

Figure 2: LPS (Lipopolysaccharide) is a toxin produced by intestinal bacteria and can translocate via the leaky epithelial barrier to the liver and damage liver cells. Thus LPS has been implicated in the pathogenesis of NASH.

INN-108, is in development for the treatment of mild-to-moderate UC. INN-108 is expected to be delivered orally using an azo-bonded pro-drug approach linking mesalamine or 5-ASA (5-amino salicylic acid) to 4-APAA (approved as Actarit in Japan in 1994 for the treatment of rheumatoid arthritis). After having completed a successful Phase 1 trial with a favorable safety profile at currently approved doses of mesalamine, INN-108 is expected to enter a proof-of-concept Phase 2 trial. The azo-bond protects INN-108 (Figure 2) from the low pH in the stomach, allowing it to transit to the colon where the UC lesions are primarily located. In the colon, the azo bond is broken enzymatically by azoreductases, leading to the separation of mesalamine and 4-APAA which has a synergistic anti-inflammatory effect. Although the majority of patients present with mild-to-moderate UC, the focus of drug development has been in moderate-to-severe UC with little innovation or drug development for mild-to-moderate UC. The mainstay of treatment for mild-to-moderate UC continues to be various oral reformulations of mesalamine such as Shire's Lialda (approved 2007) and Pentasa (approved 1993), Allergan's Asacol HD (approved 2008) and Valeant/Salix's Apriso (approved 2008).

We also own the global rights to INN-329, a proprietary formulation of secretin, a peptide hormone which is used to improve visualization in magnetic resonance cholangiopancreatography (MRCP) procedures. Secretin is a 27-amino acid long hormone which rapidly stimulates release of pancreatic secretions, thus improving visualization of the pancreatic ducts during imaging procedures.

Our Strategy

Our goal is to become a leading biopharmaceutical company by developing novel therapeutics that have the potential to transform current treatment paradigms for patients and to address unmet medical needs. We are currently pursuing the development of drugs for autoimmune and inflammatory diseases that target established biological pathways. The critical components of our strategy are as follows:

- ***Advance INN-202 (larazotide) for celiac disease into Phase 3 clinical trials.*** Our highest clinical priority is to initiate the Phase 3 trials for larazotide for the treatment of celiac disease. We had a successful End-of-Phase 2 meeting with the FDA in 2017. With the guidance and agreement reached with the FDA, we plan to initiate our Phase 3 trials during the second half of 2018.

- ***Accelerate development of INN-217 (larazotide) for NASH.*** Increased intestinal permeability leads to LPS translocation to the liver and is one of the key recognized pathogenic factors in NASH. Larazotide's mechanism of action to decrease intestinal permeability could thus have a therapeutic effect in NASH. We plan to develop larazotide alone and in combination with select NASH therapies in clinical trials with the potential for synergistic therapeutic benefit.

- ***Further the study INN-108 for Ulcerative colitis***. We are currently developing plans to initiate the proof of concept Phase 2 trials for INN-108 for the treatment of UC. We plan to initially develop INN-108 for mild-to-moderate UC in adults.

- ***Further the study of INN-289 (larazotide) for Crohn's disease.*** The mechanism of action of larazotide to decrease intestinal permeability can have a therapeutic effect in inflammatory bowel disease (IBD). In an IL-10 knockout animal model, larazotide showed promising data which can position it for a proof-of-concept study using a proprietary formulation of larazotide, INN-289, alone and in combinations with select approved immunological therapies.

- ***Seek partnerships to commercialize late stage pipeline drugs.*** With large addressable markets, such as celiac disease, we plan to seek out partners with established presences and histories of successful commercialization.

- ***Leverage and protect our existing intellectual property portfolio and secure patents for additional indications.*** We intend to continue to expand our intellectual property protection strategy, grounded in securing composition of matter patents and method of use patents for newer indications. We plan to develop newer formulations for the product candidates for other indications and improved performance of existing indications.

- ***In-license additional intellectual property and pipeline drugs to expand our presence in the treatment of autoimmune and inflammatory diseases***. In addition to broadening our current pipeline through indication expansion, we plan to explore expansion of our product pipeline through in-licensing, strategic partnerships and product acquisitions, as we did in 2016 by in-licensing of larazotide from Alba Therapeutics Corporation. We expect that future pipeline expansion decisions will be based on the unmet medical needs in autoimmune and inflammatory disease areas including, but not limited to, celiac disease and ulcerative colitis, the commercial opportunity, and the ability to rapidly develop and commercialize a product candidate.

- ***Leverage the expertise of our management team and network of scientific advisors and key opinion leaders***. We are led by a strong management team with deep experience in drug development, collaborations, operations, and corporate finance. Our team has been involved in a broad spectrum of R&D activities leading to successful outcomes, including FDA approvals and drug launches. We will continue to leverage the collective experience and talent of our management team, network of leading scientific experts, and key opinion leaders to strategize and implement our development and eventually our commercialization strategy.

- ***Out-license our non-core assets/indications and establish research collaborations***. From time to time, we review our internal research priorities and therapeutic focus areas and may decide to out-license non-core assets/indications that arise from current and future available data. We may seek research collaborations that leverage the capabilities of our core assets to monetize and expand upon the breadth of opportunities that may be accessible through our drug candidates.

- ***Outsource capital intensive operations***. We plan to continue to outsource capital intensive operations, including most clinical development and all manufacturing operations of our product candidates, to facilitate the rapid development of our pipeline by using high quality specialist vendors and consultants in a capital efficient manner.

Our Drug Product Pipeline

Our current pipeline is focused on clinical stage assets with large markets and unmet medical needs. We continue to leverage additional proof-of-concept work for larazotide to expand into additional indications, including NASH, Crohn's disease and ulcerative colitis. The following table summarizes key information about our pipeline of drug product candidates to date (Table 1):

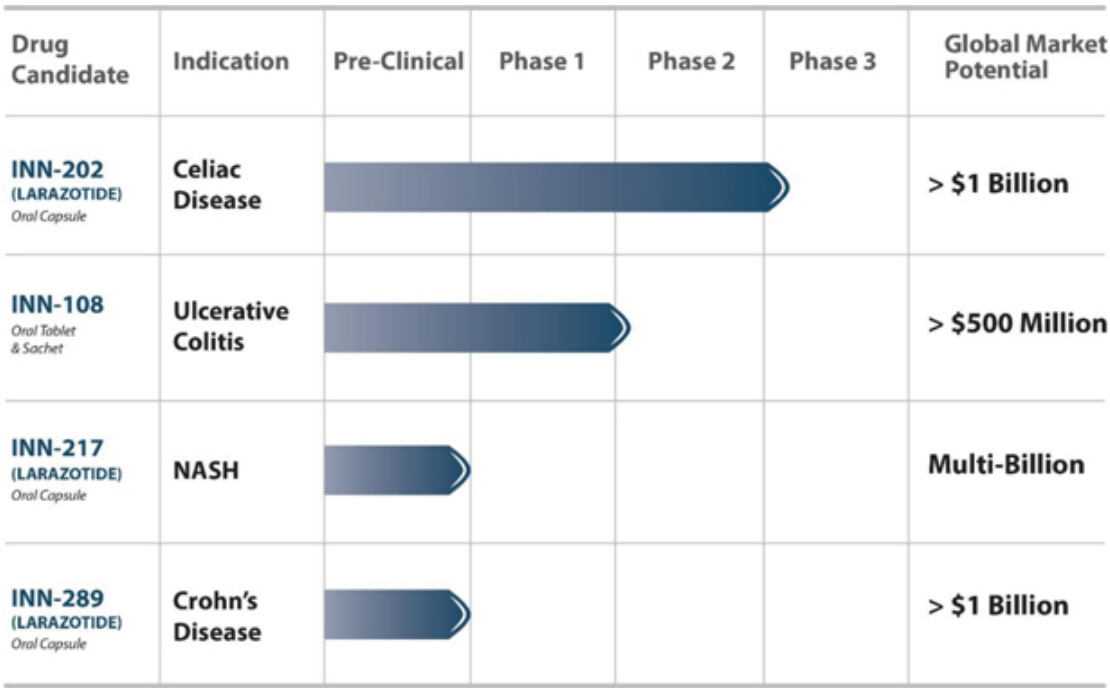

Table 1: Our key pipeline products are clinical stage and address large markets with chronically dosed therapies.

INN-202 (Larazotide) for Celiac Disease

Larazotide is being developed for the treatment of celiac disease and has successfully completed a Phase 2b trial showing statistically significant reduction in abdominal and non-GI (headache) symptoms. We are planning to launch the Phase 3 trials in the second half of 2018.

Larazotide is an orally administered, locally acting, non-systemic, synthetic 8-amino acid (Figure 3), tight junction regulator being investigated as an adjunct to a gluten-free diet in celiac disease patients who still experience persistent GI symptoms despite being on a gluten-free diet. Larazotide's favorable safety profile and the lack of absorption into the blood circulation are advantages for a chronically dosed lifetime medication.

The larazotide drug product is an enteric coated drug product formulated as enteric coated multiparticulate beads filled into hard gelatin capsules for oral delivery. The enteric coating is designed to allow the bead particles to bypass the stomach and release larazotide upon entry into the small intestine (duodenum). A mixed bead formulation is used to allow partial release of larazotide upon entry into the duodenum and to release the remaining larazotide approximately 30 minutes later. In clinical trials, larazotide has been dosed 15 minutes before meals allowing time for its effect in the small bowel before exposure to gluten.

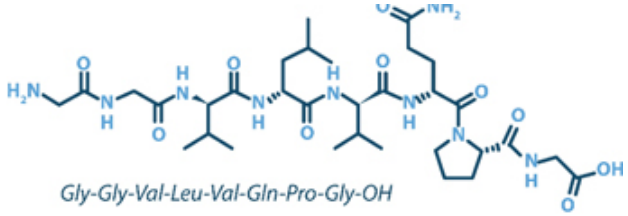

Figure 3: Larazotide acetate is an 8-amino acid peptide in an oral capsule using a proprietary formulation

Larazotide's Mechanism of Action

In research studies supportive of the mechanism of action, larazotide has been shown to stimulate recovery of mucosal barrier function via the regulation of tight junctions both *in vitro* and *in vivo*, including in a celiac disease mouse model (Gopalakrishnan, 2012). In doing so, it is proposed that larazotide reduces the symptoms associated with celiac disease.

In several autoimmune diseases, this increased intestinal permeability or paracellular leakage allows increased exposure to a triggering antigen and a consequent inflammatory response, the characteristics of which are determined by the particular disease and the genetic makeup of the individual. A new paradigm for autoimmune diseases is that there are three contributing factors to the development of disease:

1. A genetically susceptible immune system that allows the host to react abnormally to an environmental antigen;

2. An environmental antigen that triggers the disease process; and

3. The ability of the environmental antigen to interact with the immune system.

Larazotide regulates tight junction opening triggered by both gluten and inflammatory cytokines, thus reducing uptake of gluten. Larazotide also disrupts the intestinal permeability-inflammation loop, and has been shown to reduce symptoms associated with celiac disease.

Larazotide's Dose Response

Previously published *in vitro* work using Caco-2 cells has shown a linear dose response for larazotide in reducing permeability of the epithelial barrier by tightening the tight junctions (Gopalakrishnan, 2012). In several clinical trials, larazotide has exhibited clinical benefit by reducing celiac symptoms at lower doses while inhibition of this activity occurs at the higher doses. To better understand this observation, Dr. Anthony Blikslager from North Carolina State University evaluated the pharmacology of larazotide at the luminal surface of the small intestine in an *ex vivo* porcine model. A section of the porcine intestine was ligated, placed in an Ussing chamber and changes in permeability were measured by electrical resistance. Multiple experiments demonstrated that following an ischemic insult causing increased intestinal permeability, full length larazotide is capable of restoring intestinal wall integrity to that of the non-ischemic control. Subsequently, it was discovered that a specific aminopeptidase located within the brush borders of the intestinal epithelium cleaves larazotide into two fragments which lack either one or both N-terminus glycine (G) residues (**GG**VLVQPG). Both cleaved fragments, GVLVQPG and VLVQPG, do not decrease intestinal permeability. Moreover, when these two fragments are administered in combination with the active full-length larazotide, they inhibit larazotide's activity to restore intestinal wall integrity or reduce permeability. These data demonstrate that higher doses of larazotide lead to local buildup of breakdown fragments, which then compete with and block activity of larazotide after threshold concentration is reached. The *in vitro* experiments using Caco-2 monolayers did not show the same pharmacology and dose response because they lack the brush border and therefore lack the aminopeptidase which cleaves larazotide. These data also provide an explanation for the clinical observations of an optimal lower dose of larazotide, which avoids the reservoir of competing inactive fragments generated at high doses of larazotide.

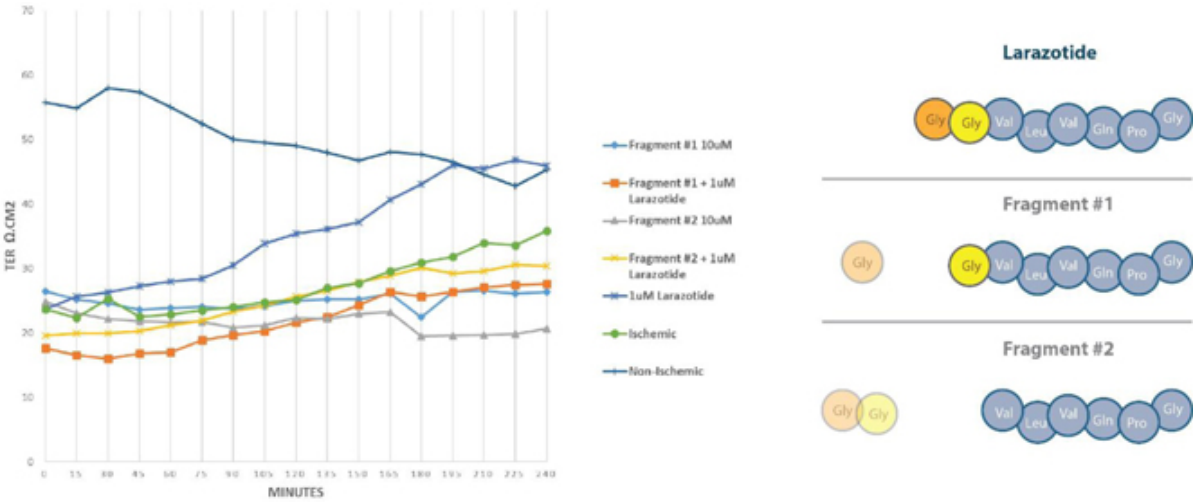

Figure 4: An aminopeptidase in the brush border cleaves larazotide into two fragments, #1 and #2, which then act as inhibitors of larazotide

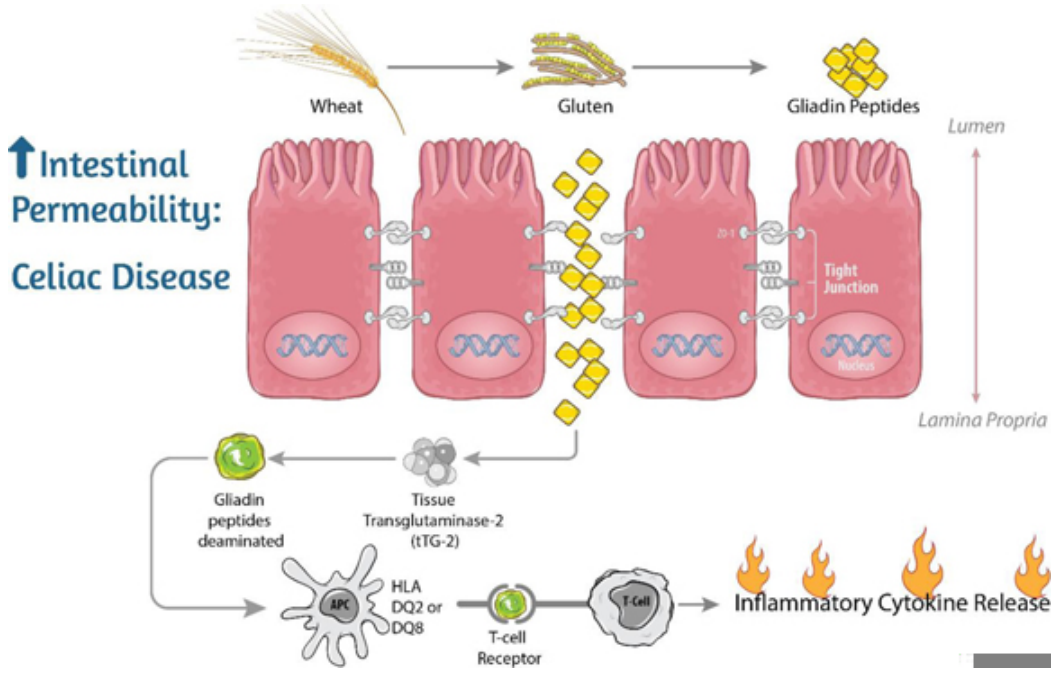

Figure 5: Illustrative effect of gluten ingestion, breakdown to gliadin which can cross a "leaky" epithelial barrier in the small bowel thus activating the intestinal-inflammatory loop and leading to symptoms and villous atrophy.

The Intestinal Barrier, Tight Junctions, and Intestinal Permeability

The intestine is one of the largest interfaces between a person and his or her environment, and an intact intestinal barrier is essential in maintaining overall health. An important function of the intestinal barrier is to regulate the trafficking of macromolecules between the environment and the host. Together with gut-associated lymphoid tissue and the neuroendocrine network, the intestinal epithelial barrier controls the equilibrium between tolerance and immunity to non self-antigens. When the finely tuned trafficking of macromolecules is dysregulated, both intestinal and extra-intestinal autoimmune disorders can occur in genetically susceptible individuals (Figure 5).

Transcellular fluxes (through the cell membrane) allow nutrients and small molecules to enter the cell from the luminal side of the intestine and exit on the serosal side (internal milieu). Paracellular fluxes (between cells) in contrast are limited by size and charge constraints imposed by the tight junctions between epithelial cells. The paracellular pathway is the key regulator of intestinal permeability to larger more complex macromolecules that may be immunogenically significant.

Intestinal epithelial cells adhere to each other through junction complexes. The tight junction, also referred to as zonula occludens, represents the major barrier to diffusion within the paracellular space between intestinal cells. Multiple proteins that make up the tight junction have been identified including occludin, claudin family members, and junctional adhesion protein (JAM). These interact with cytosolic proteins (ZO-1, ZO-2, and ZO-3) that function as adaptors between the tight junction proteins and actin and myosin contractile elements within the cell. Acting together, they open and close the paracellular junctions between cells. It is now apparent that tight junctions are dynamic structures that are involved in developmental, physiological, and pathological processes.

The role of tight junction dysfunction in the pathogenesis of autoimmune diseases is under active investigation. Many autoimmune populations have increased intestinal permeability, and it is believed that this may play a fundamental role in the development of autoimmunity. In susceptible populations, the opening of tight junctions between intestinal epithelial cells may lead to exposure to oral antigens via paracellular transport and a consequent autoimmune response. A wide range of gastrointestinal and systemic inflammatory diseases are associated with abnormal intestinal permeability including celiac disease, type 1 diabetes, inflammatory bowel diseases (Crohn's disease and UC), and ankylosing spondylitis.

Summary of Key Clinical Trials using Larazotide in Celiac Disease

Larazotide has been administered to humans in seven clinical trials. These include three Phase 1 trials: (two trials in healthy subjects and a Phase 1b proof of concept (POC) trial in subjects with celiac disease), two Phase 2 gluten challenge studies in subjects with controlled celiac disease, and additionally two Phase 2 trials in subjects with active celiac disease (Table 2). After demonstrating a favorable safety profile in the Phase 1 studies, larazotide was tested to explore which endpoint would be suitable for celiac disease. After looking at permeability changes in the gut, which turned out to be highly variable in a large trial setting, and then mucosal healing, which likely requires a longer-term study, symptom reduction showed the most consistent and reliable reduction both in a gluten challenge and a ''real-life'' trial. Importantly, after exposure in more than 800 subjects, the safety profile of larazotide remained similar to placebo due to its lack of absorption into the bloodstream, which we believe is an important advantage for a chronically dosed drug.

The initial Investigational New Drug Application (IND) for the treatment of celiac disease was filed with the FDA by Alba Therapeutics Corporation (Alba) on 12 August 2005 for the use of larazotide acetate (INN-202). The IND was transferred from Alba to Innovate effective March 8, 2016. Over the course of the seven clinical studies, 5 patients experienced a serious adverse event, of which 2 received placebo and 3 received larazotide. None of these events were considered related to treatment with study medication.

Trial	Study Date	Clinical Trial	No. of Subjects
-001	2005	Phase 1: Single Escalating Doses in Healthy Volunteers	24
-002	2005-06	Phase 1b: Multiple Dose POC in Celiac Patients – Gluten Challenge	21
-003	2006	Phase 1: Multiple Escalating Dose in Volunteers	24
-004	2006-07	Phase 2a: Multiple Dose POC in Celiac Patients Gluten Challenge 2 weeks	86
-006	2008	Phase 2b: Dose Ranging, in Celiac Patients Gluten Challenge, 6 weeks	184
-011	2008-09	Phase 2b: POC and Dose Ranging in Active Celiac Patients	105
-06B	2008	Phase 2b: Similar to -006, in Celiac Patients	42
-012	2011-13	Phase 2b: Multiple dose in Celiac patients with Symptoms on a Gluten-Free Diet	342

Table 2: Significant drug exposure in more than 800 subjects in multiple clinical trials consistently showed a safety profile similar to placebo, which we believe is an important advantage for chronic lifetime administration.

Clinical Trial (‘006) Results Revealed Key Insight into Symptom Reduction as a Primary Endpoint

A Phase 2b study with a gluten challenge (CLIN1001-006) was conducted in 184 subjects with well-controlled celiac disease on a gluten-free diet. Subjects were randomized to one of four treatment groups, (placebo, 1 mg, 4 mg, or 8 mg larazotide) and asked to take treatment 15 minutes prior to each meal (TID). Nine hundred (900) mg of gluten was taken with each meal. Subjects remained on their gluten-free diet throughout the duration of the trial. The trial results revealed key insights into how to move the program forward by focusing on reduction of symptoms. The 1-mg dose prevented the development of gluten-induced symptoms as measured by GSRS (a patient-reported outcome (PRO) devised and validated by AstraZeneca), and all drug treatment groups had lower anti-transglutaminase antibody levels than the placebo group. Results of pre-specified secondary endpoints suggest that larazotide reduced antigen exposure as manifested by reduced production of anti-tissue transglutaminase (tTG) levels and immune reactivity towards gluten and gluten-related gastrointestinal symptoms in subjects with celiac disease undergoing a gluten challenge.

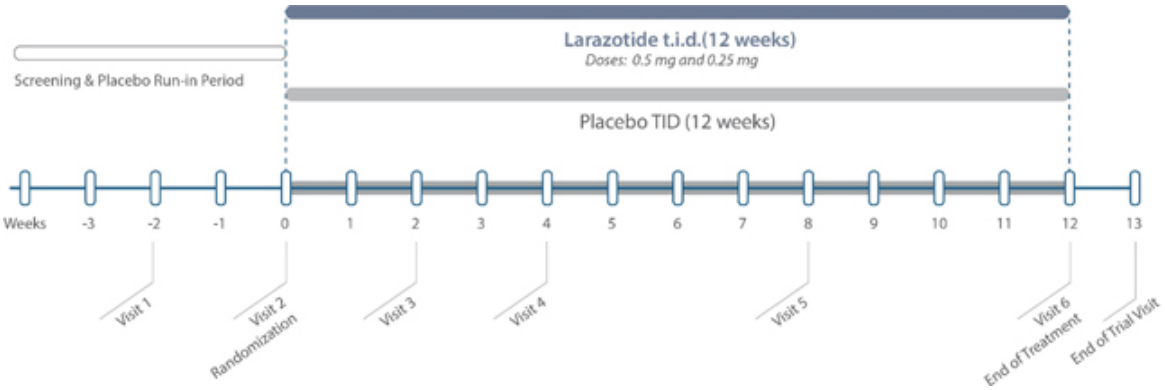

Figure 6: The overall trial designs for Phase 2b and Phase 3 are similar with a screening period followed by 12 weeks of randomization to larazotide vs. placebo.

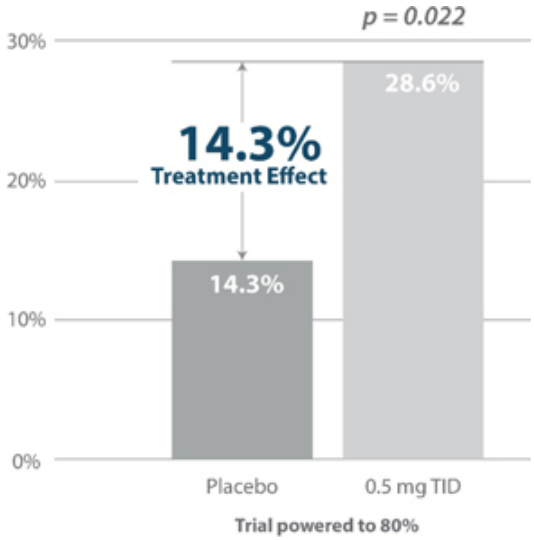

Figure 7: Responder Rate Analysis: Larazotide is the only drug in development for celiac disease to meet its primary endpoint with statistical significance as measured by the copyrighted CeD PRO (celiac disease patient reported outcome), an FDA-agreed upon primary endpoint for Phase 3 (shown above). Source: Gastroenterology 2015; 148:1311–1319; p. 1315

Clinical Trial (‘012) Met the Primary Endpoint with Statistical Significance (CeD-GSRS/CeD PRO)

The purpose of the ‘012 study was to assess the efficacy (reduction and relief of signs and symptoms of celiac disease) of 3 different doses of larazotide (0.5 mg, 1 mg, and 2 mg TID) versus placebo for the treatment of celiac disease in adults as an adjunct to a gluten-free diet. Larazotide or placebo which was administered TID, 15 minutes prior to each meal. After a screening period, subjects were asked to continue following their current gluten-free diet into a placebo-run in phase for 4 weeks after which they were randomized to drug versus placebo. Subjects maintained an electronic diary capturing: daily symptoms celiac disease patient reported outcome (CeD-PRO), weekly symptoms (CeD-GSRS), bowel movements (BSFS), and a self-reported daily general well-being assessment (Figure 6).

The primary endpoint of average on-treatment CeD GSRS score throughout the treatment period was met at the 0.5 mg TID dose. In addition, a number of pre-specified secondary and exploratory endpoints, such as symptomatic days and symptom-free days, collectively demonstrated that a dose of 0.5 mg TID was superior to placebo and higher doses of larazotide. No difference was observed between the two higher dose levels (1 and 2 mg TID) or placebo, suggesting a narrow dose range around the 0.5mg dose which seems to correlate with pre-clinical data.

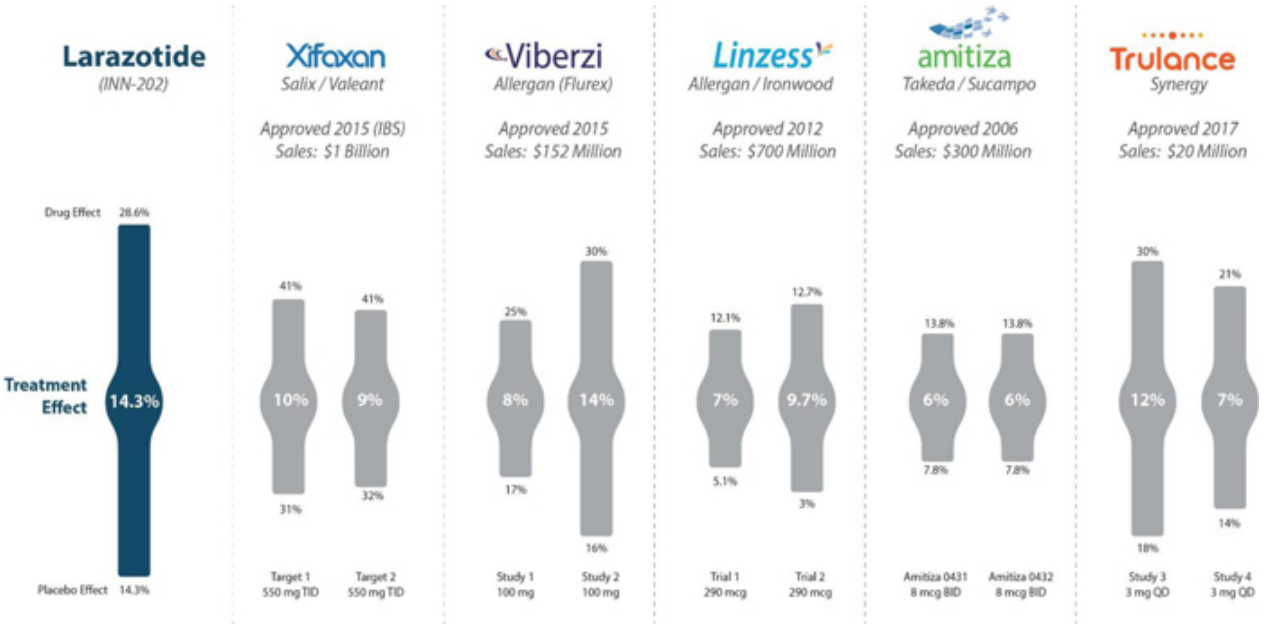

Figure 8: Treatment effect of larazotide from the Phase 2b trial ('012) compared to approved IBS/CIC drugs with varying treatment effects mostly in the mid to high single digit range. Source: Gastroenterology 2015; 148:1311–1319; p. 1315 and FDA Drug Labels

The CeD PRO, a copyrighted PRO created specifically for celiac disease and wholly owned by us, showed a statically significant (p=0.022) treatment effect of 14.3% (drug responder rate minus placebo responder rate). Although to our knowledge there are no celiac drugs approved as a comparator, the treatment effect was greater than several other GI dugs approved for IBS and chronic idiopathic constipation (CIC) which use a similar clinical trial design (Figure 8).

Path Forward to Phase 3 Trials

After a successful End-of-Phase 2 meeting with the FDA, agreements were reached on the key aspects of the Phase 3 trials. The FDA agreed on using the previously validated CeD PRO as the primary endpoint with two doses of larazotide which bracket the range of efficacy in previous trials. Two Phase 3 trials with a size of about 500 patients each would allow for more than a 90% power to replicate the Phase 2b trial results. Most other criteria, such as inclusion, exclusion and site selection/coordination, are expected to remain similar to the '012 Phase 2b trial.

About Celiac Disease

Celiac disease is a genetic autoimmune disease triggered by the ingestion of gluten-containing foods such as wheat, barley, and rye. Individuals with celiac disease have increased intestinal permeability, commonly referred to as a ''leaky'' gut. This allows macromolecules that normally remain on the luminal side of the intestine to pass through to the serosal side through tight junctions via paracellular diffusion (Figure 9). In the case of celiac disease, this permeability may allow gluten break-down products, the triggering antigens of celiac disease, to reach gut-associated lymphoid tissue(GALT), initiating an inflammatory response. Celiac disease is characterized by chronic inflammation of the small intestinal mucosa that may result in diverse symptoms, malabsorption, atrophy of intestinal villi, and a variety of clinical manifestations.

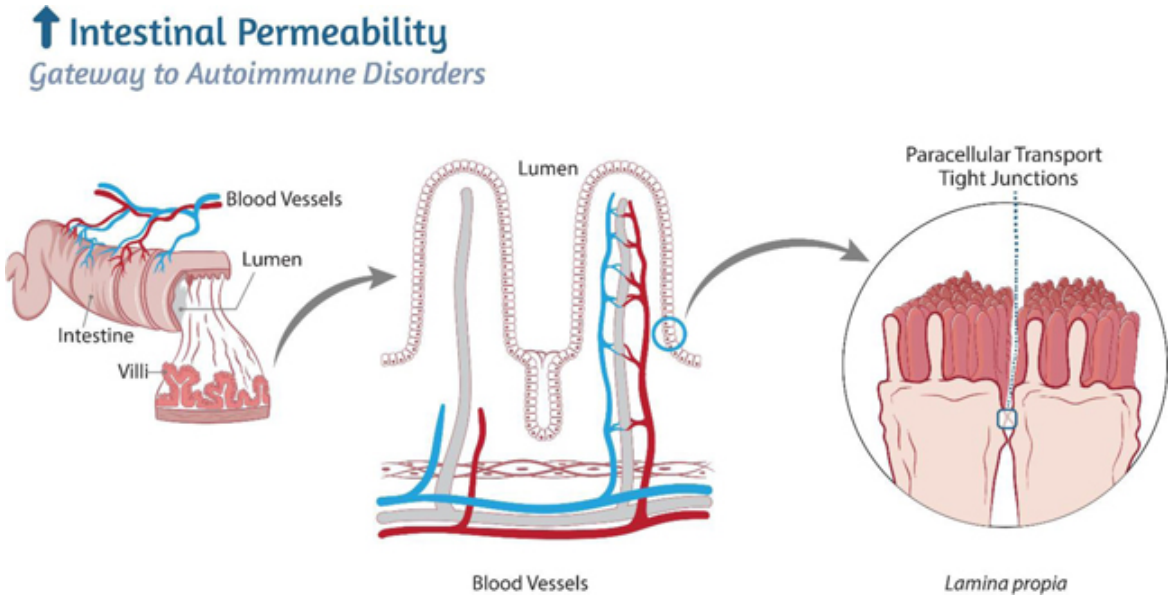

Figure 9: The epithelial barrier separates the intestinal content from the immune system (lamina propria) and the vasculature.

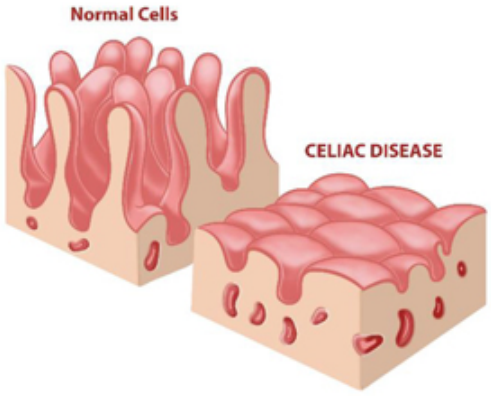

Figure 10: Intestinal villi atrophy in celiac patients, a characteristic finding upon biopsy of the small intestine.

Large Population — Unmet Need (no drug approved); Serious Long-Term Consequences

Celiac disease affects an estimated 1% of the Western population (Dubé, 2005). Currently, there are no therapeutics available to treat celiac disease, and the current management of celiac disease is a life-long adherence to a gluten-free diet. Changes in dietary habits are difficult to maintain, and foods labeled as gluten-free may still contain small amounts of gluten (up to 20 ppm per FDA labeling standards). Dietary compliance is imperfect in a large fraction of patients (Rostom, 2006) and difficult to adhere to on an ongoing basis (Green, 2007). In a survey conducted in the United Kingdom non-adherence to the gluten-free diet was found to be as high as 70% (Hall, 2013).

There are serious long-term consequences to exposure to gluten in patients with celiac disease, including the risk of developing osteoporosis, stomach, esophageal, or colon cancers, and T-cell lymphoma (Green 2003, Green 2007). The continuous GI symptoms often result in significant morbidity with a substantial reduction in quality of life. In addition, not all patients respond to a gluten-free diet. Patients with known celiac disease may continue to have or re-develop symptoms despite being on a gluten-free diet (Rostom 2006). This suggests a need for a therapeutic agent for the treatment of celiac disease (Green, 2007; Hall, 2013).

Celiac disease represents a model of an autoimmune disorder in which the following elements are known:

1. The triggering environmental factor is glutenin or gliadin, the proline, glutamine and glycine rich glycoprotein fractions of gluten;
2. There is a close genetic association with HLA haplotypes DQ2 and/or DQ8; and
3. A highly specific humoral autoimmune response occurs.

Genetics of Celiac Disease

The high incidence of celiac disease in first degree relatives of celiac patients (10 − 15%) and high concordance rate in monozygotic twins (80%) suggest a strong genetic component. Gliadin deamidation by tissue transglutaminase (tTG) enhances the recognition of gliadin peptides by human leukocyte antigen (HLA) DQ2 and DQ8 T cells in genetically predisposed subjects, which in turn may initiate the cascade of autoimmune reactions responsible for mucosal destruction. This interaction implies that gliadin and/or its breakdown peptides in some way cross the intestinal epithelial barrier and reach the *lamina propria* of the intestinal mucosa where they are recognized by antigen-presenting cells. The enhanced paracellular permeability of individuals with celiac disease would allow passage of macromolecules through the paracellular spaces with resulting autoimmune inflammation. There is a strong genetic predisposition to celiac disease, with major risk associated with HLA DQ2 (approximately 95% of celiac disease patients) and HLA-DQ8 (approximately 5% of celiac disease patients). The prevalence of celiac disease in the U.S. is estimated to be approximately 1%; however approximately 30% of the general U.S. population is HLA DQ2 positive (Figure 11), indicating that additional factors are involved in the development of celiac disease.

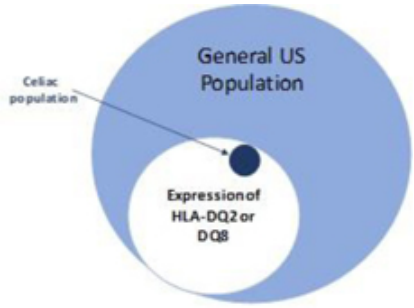

Figure 11: Distribution of HLA-DQ2/DQ8 in the general US population and in celiac disease. Source: J. Clin. Invest. 2007 Jan 2;117(1):41.

In celiac disease, an inflammatory reaction occurs in the intestine that is characterized by infiltration of immune cells in the *lamina propria* and epithelial compartments with chronic inflammatory cells and progressive architectural changes to the mucosa. Both adaptive and innate branches of the immune system are involved. The adaptive response is mediated by gluten-reactive CD4+ T cells in the *lamina propria* that recognize gluten-derived peptides when presented by the HLA class II molecules DQ2 or DQ8. The CD4+ T cells then produce pro-inflammatory cytokines such as interferon gamma. This results in an inflammatory cascade with the release of cytokines, anti-tTG antibodies, T cells, and other tissue-damaging mediators leading to villous injury and crypt hyperplasia in the intestine. Anti-human tissue transglutaminase (anti-tTG) antibodies are also produced, which form the basis of serological diagnosis of celiac disease.

Anti-tTG Antibodies: Highly Sensitive and Specific Blood-based ELISA Diagnostic Test

The current approach for diagnosis of celiac disease is to use anti-tissue transglutaminase-2 (tTG-2) antibody tests as an initial screen with definitive diagnosis from biopsy of the small intestine mucosa. The diagnosis of celiac disease is confirmed by demonstration of characteristic histologic changes in the small intestinal mucosa, which are scored based on criteria initially put forth by Marsh and later modified. In 2012, the European Society of Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) Guidelines allowed symptomatic children with serum anti-tTG antibody levels ≥10 times upper limit of normal to avoid duodenal biopsies after positive human leukocyte (HLA) test and serum anti-endomysial antibodies.

The need for multiple clinical and laboratory findings to diagnose celiac disease makes monitoring disease progression difficult. International guidelines give standardized definitions and criteria for the diagnosis of celiac disease, however there are not clear standards for follow-up and monitoring of treatment. This is particularly true for celiac patients diagnosed as adults, who respond differently and less completely to a gluten-free diet than do celiac patients diagnosed as children. It is not clear who should perform follow-up of patients with celiac disease and at what frequency but the American College of Gastroenterology suggests that an annual follow-up seems reasonable. Recommendations for monitoring disease progression include assessing symptoms and dietary compliance, and repeating serology tests. Markers of celiac disease progression and improvement that are both validated and provide a timely assessment of disease activity are lacking.

Role of Tissue Transglutaminase in Celiac Disease

Anti-tTG-2 antibodies are produced in the small-intestinal mucosa (Picarelli et al. 1996), where they can bind tTG-2 present in the basement membrane and around blood vessels and form deposits characteristic of the disease. tTG-2 has been implicated in a variety of human disorders including several neurodegenerative conditions and cancer. Transglutaminases (TGs) were first discovered in the 1950s and are a family of enzymes which catalyze Ca2+-dependent post-translational modification of proteins. Of the seven isoforms discovered so far all share the same basic four-domain tertiary structure, with minor variations, although their catalytic mechanism is conserved, resembling that of the cysteine proteases. tTGs cause transamidation, esterification, and hydrolysis, all of which lead to post-translational modifications in the target proteins. Characteristically, tTG's mediate selective protein cross-linking by forming covalent isopeptide linkages between two target proteins. The resulting cross-linked products in many cases have high molecular masses and are unusually resistant to proteolytic degradation and mechanical strain. As in the case of the gliadin fragments in celiac disease, they are able to pass thru the leaky paracellular pathway from the lumen to the *lamina propria*, where the immune cells reside and are then activated.

Gliadin fragments, in addition to being rich in proline, also have high glutamine content, which makes them suitable substrates for tTG-2, which targets glutamine residues. For augmented DQ2/8 binding, the conversion of glutamine residues to glutamic acid is catalyzed by tTG-2 as a deamidation reaction. After deamidation, the gliadin peptides become highly negatively charged in key anchor positions, thereby increasing their affinity to the HLA molecules. CD4+ T cells recognize the deamidated gliadin peptides bound to the HLA DQ2 or DQ8 molecules by their T cell receptors, thus activating intestinal inflammation leading to villous atrophy.

Gluten and Food Labeling

Gluten is a complex molecule contained in several grains such as wheat, rye and barley. Gluten can be subdivided into two major protein subgroups according to its solubility in alcohol and aqueous solutions. These subclasses consist of gliadins, soluble in 40 − 70% ethanol and glutenins which are large, polymeric molecules insoluble in both alcohol and aqueous solutions. The gliadins and glutenins can be further subdivided into groups according to their molecular weight. Glutenins can be subdivided into low and high molecular weight proteins, while the gliadin protein family contains α-, β-, γ- and ω- types. Both glutenins and gliadins are characterized by a high amount of prolines (20%) and glutamines (40%) that protect them from complete degradation in the gastrointestinal tract and make them difficult to digest. Currently 31 nine-amino acid peptide sequences in the prolamins of wheat and related species have been defined as being celiac toxic or celiac ‘‘epitopes.’’ These epitopes are located in the repetitive domains of the prolamins, which are proline and glutamine-rich, and the high levels of proline make the peptide resistant to proteolysis. In addition, the prolamin-reactive T cells also recognize these epitopes to a greater extent when specific glutamine residues in their sequences have been deamidated to glutamic acid by tTG-2. The immunodominant sequence after wheat challenge corresponds to a well-characterized 33 residue peptide from α-gliadin, ‘‘33-mer,’’ that is resistant to gastrointestinal digestion (with pepsin and trypsin) and was initially identified as the major celiac toxic peptide in the gliadins.

The FDA finalized a standard definition of ‘‘gluten-free’’ in August 2013. As of August 5, 2014, all manufacturers of FDA-regulated packaged food making a gluten-free claim must comply with the guidelines outlined by the FDA (*www.fda.gov/gluten-freelabeling*). A ‘‘gluten free’’ claim still allows up to 20 ppm of gluten which leads to more than 100mg/day up to 500 mg/day of gluten exposure. Due to presence of gluten in foods, beer/liquor, cosmetics and household products, exposure is virtually impossible to completely avoid, and with cross-contamination, celiac patients cannot avoid exposure to gluten therefore, making symptoms more frequent than expected.

CNS	Endocrine	Oncology/Heme	Skin	Other
Headaches	Type 1 Diabetes	Enteropathy associated T-cell lymphoma (EATL)	Dermatitis herpetiformis	Rheumatoid arthritis (RA)
Gluten ataxia	Autoimmune Thyroid	anemia	Alopecia areata	Reduced bone Density
Peripheral neuropathies	Addison’s disease		Vitiligo	Sjogren’s syndrome

Table 3: Diseases associated with celiac disease

Non-GI Manifestations of Celiac Disease and Co-Morbidities

Headache, Gluten Ataxia: Nervous System Manifestation of Celiac Disease. The association between celiac disease and neurologic disorders has been supported by numerous studies over the past 40 years. While peripheral neuropathy and ataxia have been the most frequently reported neurologic extra-intestinal manifestations of celiac disease a growing body of literature has established headache as a common presentation of celiac disease as well. The exact prevalence of headache among patients ranges from about 30% to 6% (Lebwohl, 2016).

Dermatitis herpetiformis: Skin Manifestation of Celiac Disease. Dermatitis herpetiformis (DH) is an inflammatory cutaneous disease characterized by intensely pruritic polymorphic lesions with a chronic-relapsing course, first described by Duhring in 1884. DH’s only treatment is a strict lifelong gluten-free diet, for achieving and maintaining a permanent control. It appears in around 25% patients with celiac disease, at any age of life, mainly in adults and is a very characteristic clinical presenting symptom.

INN-217: Non-alcoholic steatohepatitis (NASH) and The Microbiome

NASH is a growing epidemic affecting approximately 5 – 6% of the general population. An additional 10% to 20% of the general population who ingest little (< 70 g/week for females and <140 g/week for males) to no alcohol are characterized with fat accumulation in the liver, without inflammation or damage, a condition called nonalcoholic fatty liver disease (NAFLD). The progression of fatty liver to NAFLD to NASH to cirrhosis is a serious condition which has no approved FDA treatment. Evidence supporting a role for the gut-liver axis in the pathogenesis of NAFLD/NASH has been accumulating over the past 20 years. LPS or endotoxin translocation is thought to be a primary cause of downstream signaling in the liver causing inflammation and damage. NASH is associated with increased gut permeability caused by disruption of intercellular tight junctions in the intestine allowing LPS from bacteria to pass into the portal circulation to the liver directly damaging hepatocytes. LPS constitutes the outer leaflet of the outer membrane of most gram-negative bacteria. LPS is comprised of a hydrophilic polysaccharide and a hydrophobic component known as lipid A which is responsible for the major bioactivity of endotoxin. When released and translocated into the bloodstream from the gut, LPS can cause a variety of cytokine activity and inflammation in the host.

The disrupted barrier along with an altered microbiome in the gut contribute to NASH as recently demonstrated by a group from Emory University, Rahman *et. al.*, in *Gastroenterology* (2016). Knockout mice missing the junctional adhesion molecule A (JAM-A) (*F11r-/-*), which have a defect in the intestinal epithelial barrier thus making it “leaky,” develop more severe steatohepatitis. JAM-A is a component of the tight junction complex that regulates intestinal epithelial paracellular permeability. *F11r-/-* mice therefore have leaky tight junctions that allow for translocation of gut bacteria to peripheral organs. By restoring the leaky tight junctions, larazotide could potentially have a beneficial therapeutic effect by blocking translocation of bacterial toxins via the paracellular pathway and may also help normalize the dysbiotic microbiome found in NASH.

Significant growth in the market for NASH therapeutics is expected according to Global Data’s research across the major markets of the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan, with these markets expected to grow to around $25.3 billion by 2026. By affecting the tight junctions in the intestinal epithelium, larazotide, a non-absorbable peptide with an established favorable safety profile in human subjects, has a potentially synergistic therapeutic effect due to its mechanism of action, could act alone or in combination with the multitude of NASH compounds in clinical trials.

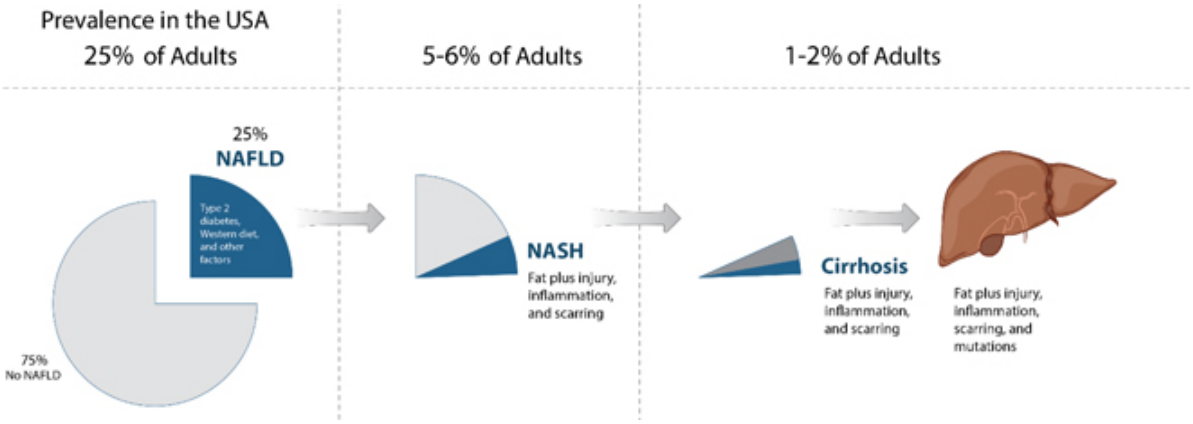

Figure 12: Growing NASH population up to 5%-6% of adults in the US alone.

INN-289: Crohn’s Disease: Chronic Disease with need to oral therapeutics

Innovate is working on a proprietary formulation of larazotide for Crohn’s disease, INN-289. Animal data has shown the effect of larazotide on disease attenuation in an IL-10 knockout mouse model (Arrieta, 2009), which has been well established and used for several drug development programs. Larazotide was placed in the drinking water of the mice at a low dose (0.1 mg/ml) or high dose (1.0 mg/ml) during the period from 4 to 17 weeks of age. Results were compared to wild type mice, IL-10 knockout mice with no treatment, and IL-10 knockout mice treated with probiotics. Intestinal and colonic permeability was significantly reduced in the high dose larazotide treatment group, but not in the untreated IL-10 knockout group. Larazotide treatment caused a reduction in all tissue markers of colonic inflammation (IFNγ and TNFα) and in histological inflammation.

Other Indications using Larazotide's Mechanism of Action

Larazotide for Environmental Enteric Dysfunction (EED): Positive in vitro Data;

Environmental enteric dysfunction (EED) is a rare pediatric tropical disease in the U.S. and Europe, however, more than 165 million children in developing countries in Africa and Asia suffer from it. As per section 524 of the Federal Food, Drug, and Cosmetic Act (FD&C) Act, EED would likely fall under ''Current List of Tropical Disease'' number 'S,' thus making a drug approved for EED in the U.S. potentially eligible for a Priority Review Voucher.

The histological presentation of EED is very similar to celiac disease with villous atrophy and chronic inflammation of the small bowel and the pathogenesis of EED is linked to increased intestinal permeability. We have tested larazotide against some of the pathogens commonly found in EED (unpublished) and found positive *in vitro* results which will need to be confirmed in animal models before starting a clinical trial in EED.

INN-108: Mild-to-Moderate Ulcerative Colitis

INN-108 is in development for mild-to-moderate UC and is expected to enter a proof-of-concept Phase 2 trial in the second half of 2018 after a successful Phase 1 trial demonstrating a favorable safety profile at currently approved doses of mesalamine. UC is an IBD that affects more than 1.25 million people in the major markets of the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan and is characterized by inflammation and ulcers in the colon and rectum. UC is a chronic disease that can be debilitating and sometimes lead to life-threatening complications. While poorly understood, a multitude of environmental factors and genetic vulnerabilities are thought to lead to the dysregulation of the immune response via a defective epithelial barrier. Although the majority of patients present with mild-to-moderate UC which can progress to severe UC, the focus of drug development has been in moderate-to-severe UC with little innovation or drug development for mild-to-moderate UC. The mainstay of treatment for mild-to-moderate UC remain various oral reformulations of mesalamine or 5-ASA (5-amino salicylic acid) such as Shire's Lialda (approved 2007) and Pentasa (approved 1993), Allergan's Asacol HD (approved 2008) and Valeant/Salix's Apriso (approved 2008).

The initial IND was filed with the FDA by Nobex Corporation on 15 May 2003 for the use of APAZA (INN-108) for the treatment of ulcerative colitis. The IND was then transferred from Seachaid Corporation to Innovate effective 19 March 2014. Two Phase 1 studies in healthy subjects and patients with ulcerative colitis were conducted by Nobex with INN-108. No serious adverse events were reported during either study.

INN-108 uses an azo-bonded pro-drug approach linking mesalamine to 4-APAA. Mitsubishi Pharma developed 4-APAA as Actarit in Japan which was approved in 1994 for rheumatoid arthritis. IBD drugs were all originally approved for RA, from the oldest 5-ASA, sulfasalazine, to the latest biologics, Humira and Enbrel. 4-APAA has more than two decades of safety data as a standalone drug and has an MoA which is differentiated from mesalamine though the ultimate effect for both is anti-inflammatory (Figure 13). Taken orally as a tablet, the azo-bond protects INN-108 from the low pH in the stomach, thus allowing it to transit to the colon where the UC lesions are located. In the colon, the azo bond is broken enzymatically leading to the release of mesalamine and 4-APAA which have a synergistic anti-inflammatory effect. With the addition of 4-APAA, which is not approved in the U.S. or EU, to the already approved mesalamine, the synergistic effect could lead to superior clinical efficacy over the currently approved oral mesalamines.

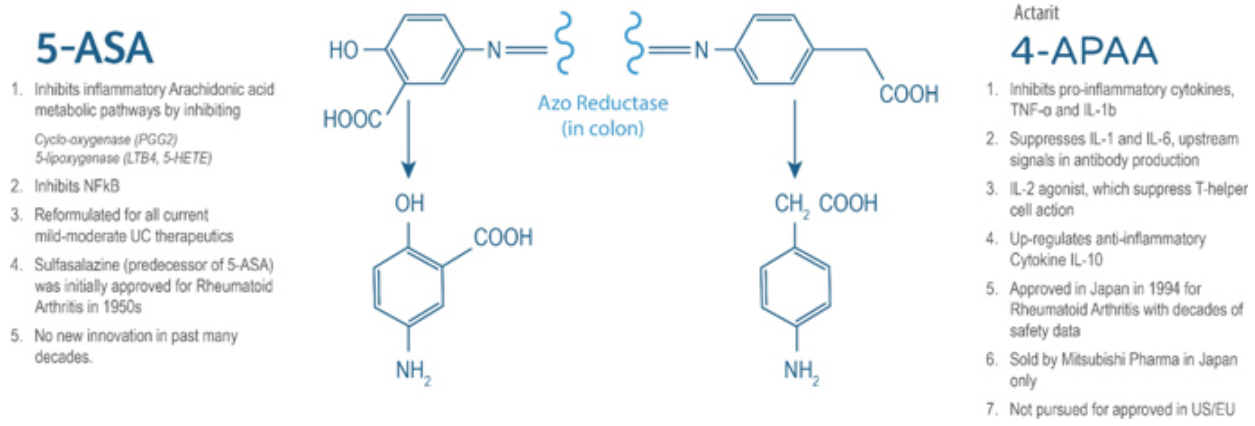

Figure 13: 4-APAA is covalently bonded to 5-ASA via a high energy azo-bond which is only enzymatically cleaved in the colon. The anti-inflammatory effect of each of 5-ASA and 4-APAA via different pathways which could lead to a potential synergistic anti-inflammatory effect as seen in animal studies.

INN-108: UC Animal Model Data Shows Synergy between 4-APAA and Mesalamine

The effects of chronic treatment with INN-108 on *Clostridium difficile* toxin A — induced colitis of the colon is shown in Figure 14. Orally administered INN-108 was significantly more potent than sulfasalazine or 4-APAA alone (McVey, 2005).

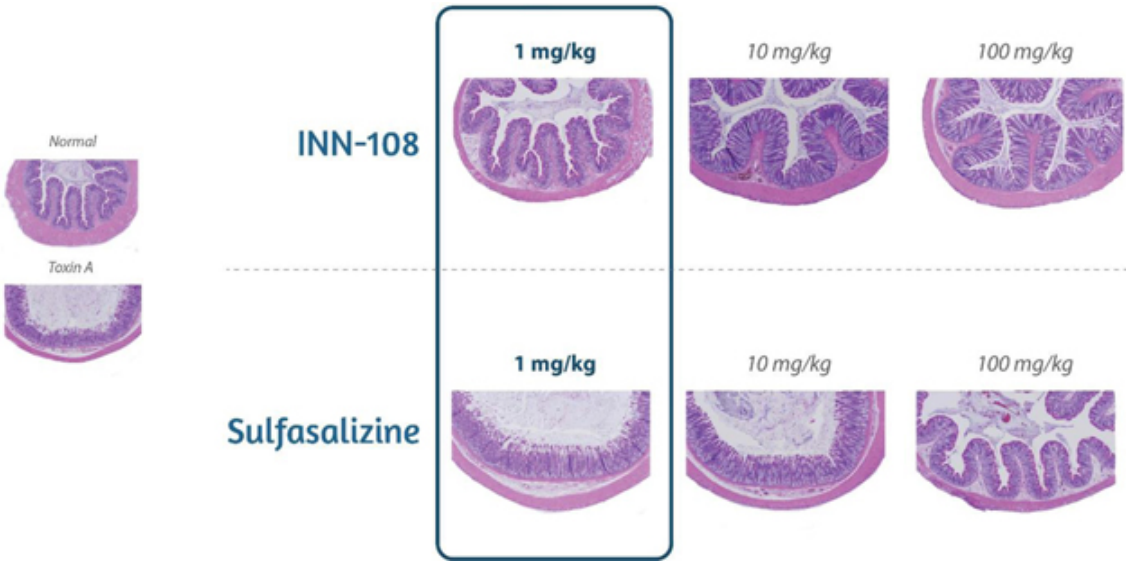

Figure 14: A rat UC model using toxin A induced-colitis as the insult leads to sloughing of the colonic epithelium with increasing doses. Using sulfasalazine vs. INN-108 to protect against the toxin A injury showed INN-108 was significantly more potent that sulfasalazine. Source: McVey DC et al. Digestive Diseases and Sciences. 2005 Mar 1;50(3):565-73.

INN-108 Clinical Development Pathway

After completing a Phase 1 study with 24 subjects, a favorable safety profile was established with dosing of mesalamine and 4-APAA at 2 grams each for a total of 4 grams TID. The typical dose of the various approved mesalamine formulations range from 1.5g to 2.4g per day, thus INN-108's mesalamine content is within the established approved dose range. The addition of 4-APAA is thought to improve the efficacy above mesalamine, which would allow INN-108 to be used either after or instead of current mesalamines. In a Phase 2 trial, we plan to compare INN-108 to mesalamine seeking to demonstrate a greater clinical effect than mesalamine alone.

Ulcerative Colitis: Lack of Innovation in New Drug Development for Past Several Decades

Conventional therapies broadly inhibit mechanisms involved in the inflammatory process and are commonly used to effectively treat patients experiencing a mild-to-moderate form of the disease. For mild-to-moderate UC, oral mesalamine has an established efficacy and safety profile. However, gastroenterologists cite the need for new therapies for mild-to-moderate UC.

Patients who do not respond to mesalamine are typically eventually transitioned to biologics. The primary targets for biologics have been to control the immune response and inflammatory cascade, by inhibiting or downregulating molecules such as TNF-α, NF-κB, IL-1β and IFN1-γ. We believe INN-108 bridges the gap between mesalamine and biologics by its mechanism of action of both inhibiting the inflammatory process and down-regulating the cytokines.

About Ulcerative Colitis

UC is a chronic intermittent relapsing inflammatory disorder of the large intestine and rectum. While poorly understood, a multitude of environmental factors and genetic vulnerabilities are thought to lead to the dysregulation of the immune response via a defective epithelial barrier. As a result, chronic inflammation and ulceration of the colon occurs. UC is specific to the colon and affects only the mucosal lining of the colon. Common symptoms of UC include diarrhea, bloody stools, and abdominal pain. The majority of patients are intermittent in their disease course, in that they experience a relapse among periods of remission. However, some patients experience only a single episode of the disease prior to maintaining remission whereas other patients are chronically symptomatic and may require a proctocolectomy to treat their condition.

History of Drug Development in Mild-to-Moderate Ulcerative Colitis

The original compound used in UC was sulfasalazine (Azulfidine), a conjugate of 5-ASA linked to sulfapyridine by an azo bond, which is split into the two molecules by bacterial azoreductases in the colon. The 5-ASA component or mesalamine is the active therapeutic moiety of sulfasalazine, with sulfapyridine thought to have little if any therapeutic effect. Sulfapyridine, however, is the cause of most of the significant adverse side effects of sulfasalazine.

This led to the development of other 5-ASA preparations utilizing azo chemistry to deliver high concentrations of mesalamine or 5-ASA to the colon by preventing early absorption of the drug in the small intestine. Such preparations include olsalazine (Dipentum), consisting of two molecules of 5-ASA bonded together by an azo bond, and balsalazide (Colazal), consisting of 5-ASA azo bonded to an inert carrier (4-aminobenzoyl-β-alanine). The efficacy of these newer oral forms of 5-ASA is comparable to that of sulfasalazine, but they are better tolerated. However, some side effects persist which prevent wider use. In each of these preparations, the only active moiety is mesalamine or 5-ASA, an anti-inflammatory agent.

INN-329

INN-329 is a proprietary formulation of secretin, a peptide hormone which is used to improve visualization in a magnetic resonance cholangiopancreatography (MRCP) procedures. Secretin is a 27-amino acid long hormone which rapidly stimulates release of pancreatic secretions, thus improving visualization of the pancreatic ducts during imaging procedures. Secretin has also been tested in a variety of central nervous system conditions such as autism, though currently approved only for pancreatic function testing and imaging with endoscopic retrograde cholangiopancreatography (ERCP).. We acquired the assets of secretin from Repligen Corporation in December 2014.

The initial IND and was filed with the FDA by Repligen on July 29, 2005 for MRCP. The IND was transferred from Repligen to Innovate in January 2015. The New Drug Application (NDA) for MRCP was filed with the FDA on December 21, 2011 and was transferred to Innovate in January 2015.

MRCP has been used for more than 20 years as a non-invasive tool for imaging pancreatic ducts. With the addition of secretin pancreatic secretions are increased leading to significantly improved visualization of the pancreatic ducts for detection of abnormalities, including pancreatic cancer. The gold standard for pancreatic duct imaging had been ERCP, an expensive and invasive procedure with complications such as pancreatitis (3 − 5%), bleeding (1 − 2%), perforation (1%), infection (1 − 2%) and death (1/250). More than a half-million ERCP procedures are performed annually in the U.S. and as the role of ERCP diminishes for screening, it will further the need for approval of secretin for S-MRCP. We expect to repeat a Phase 3 trial with a partner, if and when secured, as per previous discussion with the FDA to look at improvement in visualization of the pancreatic duct via MRCP with and without secretin.

Our Intellectual Property

We strive to protect the proprietary technology that we believe is important to our business, including our product candidates and our processes. We seek patent protection in the United States and internationally for our product candidates, their methods of use, and processes of manufacture and any other technology to which we have rights, as appropriate. Additionally, we have licensed the rights to intellectual property related to certain of our product candidates, including patents and patent applications that cover the products or their methods of use or processes of manufacture. The terms of the licenses are described below under the heading “Licensing Agreements.” The patent families related to the intellectual property covered by the licenses include 29 U.S. patents and 107 foreign patents with expiration dates ranging from 2018 to 2035. We also rely on trade secrets that may be important to the development of our business.

Our success will in part depend on the ability to obtain and maintain patent and other proprietary rights in commercially important technology, inventions and know-how related to our business, the validity and enforceability of our patents, the continued confidentiality of our trade secrets, and our ability to operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be sure that any of our existing patents or any patents we may own or license in the future will be useful in protecting our technology and products. For this and more comprehensive risks related to our intellectual property, please see “Risk Factors—Risks Related to Our Intellectual Property.”

CeD PRO: Copyrighted Primary Endpoint for Celiac Disease Tested in a Successful Clinical Trial

The patient reported outcome (PRO) primary end point for celiac disease (CeD PRO) was developed based on FDA guidance and is copyrighted in the United States effective October 13, 2011. The copyright registration is in effect for 95 years from the year of first publication or 120 years from the year of creation, whichever expires first. If the drug is approved by the FDA and is the first drug to be approved for celiac disease, Innovate believes that the PRO will become the standard for assessing efficacy in celiac disease. Competitor companies seeking to use a PRO to establish efficacy in this indication would either need to develop their own PRO or would be required to license the CeD PRO from Innovate, thus providing an additional barrier to competitor entry into the marketplace.

Strategic Collaborations and License Agreements

We have entered into collaboration agreements with several academic institutions and other contract research organizations to investigate pre-clinical studies for the use of our product candidates in potential other indications or to further broaden our understanding of the current indications.

Licensing Agreements

License with Alba Therapeutics Corporation

In February 2016, we entered into a license agreement (the ”Alba License”) with Alba Therapeutics Corporation (“Alba”) to obtain an exclusive worldwide license to certain intellectual property relating to larazotide and related compounds.

Our initial area of focus for this asset relates to the treatment of celiac disease. We now refer to this program as INN-202. The license agreement gives us the rights to (i) patent families owned by University of Maryland, Baltimore (UMB) and licensed to Alba, (ii) certain patent families owned by Alba, and (iii) one patent family that is jointly owned. In connection with the Alba License, we also entered into a sublicense agreement with Alba under which Alba sublicensed the UMB patents to us (the “Alba Sublicense”).

As consideration for the Alba License, we agreed to pay (i) a one-time, non-refundable fee of $0.4 million at the time of execution and (ii) set payments totaling up to $151.5 million upon the achievement of certain milestones in connection with the development of the product, which milestones include the dosing of the first patient in the Phase 3 clinical trial, acceptance and approval of the New Drug Application, the first commercial sale, and the achievement of certain net sales targets. The last milestone payment is due upon the achievement of annual net sales of INN-202 in excess of $1.5 billion. Upon the first commercial sale of INN-202, the license becomes perpetual and irrevocable. The term of the Alba Sublicense, for which we paid a one-time, non-refundable fee of $0.1 million, extends until the earlier of (i) the termination of the Alba License, (ii) the termination of the underlying license agreement, or (iii) an assignment of the underlying license agreement to us. After we make the first milestone payment after the dosing of the first patient in the Phase 3 clinical trial and are able to demonstrate sufficient financial resources to complete the trial, we have the exclusive option to purchase the assets covered by the license.

The patents covering the composition-of-matter for the larazotide peptide expire in 2018 (2019 outside the United States). The Alba Therapeutics patent estate nevertheless provides product exclusivity for INN-202 in the U.S. until June 4, 2031, not including patent term extensions that may apply upon product approval.

The INN-202 patent estate includes issued patents in the U.S. for methods of treating celiac disease with larazotide, of which the last to expire has a term to July 16, 2030. The INN-202 patent estate further includes patents covering the composition-of-matter and corresponding methods of treatment for the larazotide formulation, with the last to expire patent having an expiration in the U.S. of June 4, 2031. The larazotide formulation patent family (ALB-015) has three issued U.S. patents, as well as 39 filings outside the U.S. (31 issued).

License with Seachaid Pharmaceuticals, Inc.

In April 2013, we entered into a license agreement (the "Seachaid License") with Seachaid Pharmaceuticals, Inc. ("Seachaid") to further develop and commercialize the licensed product, the compound known as APAZA. This program is now referred to as INN-108 by us.

The license agreement gives us the exclusive rights to (i) commercialize products covered by the patents owned or controlled by Seachaid related to the composition, formulation or use of any APAZA compound in the territory that includes the U.S., Canada, Japan, and most countries in Europe, and (ii) use, research, develop, export and make products worldwide for the purposes of such commercialization.

As consideration for the Seachaid License, we agreed to pay a one-time, non-refundable fee of $0.2 million at the earlier of the time we meet certain financing levels or 18 months following the execution of the agreement and set payments totaling up to $6.0 million upon the achievement of certain milestones in connection with the development of the product, filing of the New Drug Application, the first commercial sale, and payments ranging from $1.0 million to $2.5 million based on the achievement of certain net sales targets. There are future royalty payments in the single digits based on achieving sales targets, and we are required to pay Seachaid a portion of any sublicense revenue. The royalty payments continue for each licensed product and in each applicable country until the earlier of (i) the date of expiration of the last valid claim for such products to expire or (ii) the date that one or more generic equivalents if such product makes up 50 percent or more of sales in the applicable country. The term of the Seachaid License extends on a product-by-product and country-by-country basis until the expiration of the royalty period for the applicable product in the applicable country.

The INN-108 patent estate includes issued patents for:

(i.) immunoregulatory compounds and derivatives and methods of treating diseases therewith, of which the last to expire has a term to December 17, 2021 (in the U.S.) and August 28, 2021 (in Europe);
(ii.) methods and compositions employing 4-aminophenylacetic acid, of which the last to expire has a term to to August 29, 2021 (in the U.S.);
(iii.) 5-ASA derivatives having anti-inflammatory and antibiotic activity, of which the last to expire has a term to August 29, 2021 (in the U.S.) and August 28, 2021 (in Europe); and
(iv.) synthesis of azo bonded immunoregulatory compounds, of which the last to expire has a term to May 31, 2028 (in the U.S.) and July 7, 2025 (in Europe).

The corresponding European patent application for (ii.) methods and compositions employing 4-aminophenylacetic acid is still pending, but if issued would provide a term to March 22, 2025 in the countries where the application is validated.

The INN-108 patent estate includes also provisional patent applications for pharmaceutical compositions, delivery compositions, methods of prophylaxis and methods of treatment. These patent applications have not yet been issued, and so it is impossible to know the expiration date of any intellectual property that might result from these applications.

Asset Purchase Agreement

In December 2014, we entered into an Asset Purchase Agreement (the "Asset Purchase Agreement") with Repligen Corporation ("Repligen") to acquire Repligen's RG-1068 program for the development of secretin for the pancreatic imaging market and MRCP procedures. We now refer to this program as INN-329. As consideration for the Asset Purchase Agreement, we agreed to make a non-refundable cash payment on the date of the agreement and future royalty payments consisting of a percentage of annual net sales, with the royalty payment percentage increasing as annual net sales increase. The royalty payments are made on a product-by-product and country-by-country basis and the obligation to make the payments expires with respect to each country upon the later of (i) the expiration of regulatory exclusivity for the product in that country or (ii) ten years after the first commercial sale in that country. The royalty amount is subject to reduction in certain situations, such as the entry of generic competition in the market.

Manufacturing and Supply

We contract with third parties for the manufacturing of all of our product candidates, including INN-108, INN-202 and INN-329, for pre-clinical and clinical studies and intend to continue to do so in the future. We do not own or operate any manufacturing facilities, and we have no plans to build any owned clinical or commercial scale manufacturing capabilities. We believe that the use of contract manufacturing organizations (CMOs) eliminates the need to directly invest in manufacturing facilities, equipment and additional staff. Although we rely on contract manufacturers, our personnel or consultants have extensive manufacturing experience overseeing CMOs.

As we further develop our molecules, we expect to consider secondary or back-up manufacturers for both active pharmaceutical ingredient and drug product manufacturing. To date, our third-party manufacturers have met the manufacturing requirements for our product candidates in a timely manner. We expect third-party manufacturers to be capable of providing sufficient quantities of our product candidates to meet anticipated full-scale commercial demands but we have not assessed these capabilities beyond the supply of clinical materials to date. We currently engage CMOs on a ''fee for services'' basis based on our current development plans. We plan to identify CMOs and enter into longer term contracts or commitments as we move our product candidates into Phase 3 clinical trials.

We believe alternate sources of manufacturing will be available to satisfy our clinical and future commercial requirements; however we cannot guarantee that identifying and establishing alternative relationships with such sources will be successful, cost effective, or completed on a timely basis without significant delay in the development or commercialization of our product candidates. All of the vendors we use are required to conduct their operations under current Good Manufacturing Practices, or cGMP, a regulatory standard for the manufacture of pharmaceuticals.

Commercialization

We own or control exclusive rights to all three of our product candidates in the markets of the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. We plan to pursue regulatory approvals for our products in the United States and the European Union, and may independently commercialize these products in the United States. In doing so, we may engage strategic partners to assist with the sales and promotion of our products.

Our anticipated commercialization strategy in the United States would target key prescribing physicians, including specialists such as gastroenterologists, as well as provide patients with support programs to ensure product access. Outside of the United States, we plan to seek partners to commercialize our products via out-licensing agreements or other similar commercial arrangements.

Competition

The pharmaceutical industry is highly competitive and characterized by intense and rapidly changing competition to develop new technologies and proprietary products. Our potential competitors include both major and specialty pharmaceutical companies worldwide. Our success will be based in part on our ability to identify, develop and manage a portfolio of product candidates that are safer and more effective than competing products.

The competitive landscape in celiac disease is currently limited, which we believe is due to lack of significant past R&D investments and lack of recognition and education around the disease. To our knowledge, there are no late stage competitors entering Phase 3 clinical trials or any who have successfully completed Phase 2 studies to date. However, in recent years large pharmaceutical companies have begun to expand their focus areas to autoimmune diseases such as celiac disease, and given the unmet medical needs in these areas, we anticipate increasing competition. A few early stage programs are active, with time to enter Phase 1 clinical trials still several years away, including Roche/Genetech's RG7625 (cathepsin S inhibitor), Takeda/PvP's KumaMax (gluten degrading enzyme), Celimmune/Amgen's AMG-714 (an IL-15 MAb) and Dr. Falk Pharma/Zeria's ZED-1227 (a tTG-2 inhibitor). ImmunogenX's IMGX003 (two gluten degrading enzymes) failed to meet its primary endpoint in a Phase 2b trial in 2015.

Product	Status	Mechanism	Company	Route	Product Type
AMG 714	Phase 2	Anti-IL-15 MAb	Celimmune/ Amgen	Subcutaneous; 2x/month	MAb (humanized)
ZED-1227	Phase 1b	TGase-2 inhibitor	Zedira GmbH/ Dr Falk Pharma	Oral	Small molecule (peptidomimetic)
Nexvax2	Phase 1	Tolerizing vaccine	ImmusanT	Intradermal	3 gliadin epitopes (peptides)
KumaMax	Pre-clinical	Enzymatic degradation of gluten	Takeda/PvP Biologics	Oral	Recombinant enzyme

Table 4: Current celiac drugs in development are still in pre-clinical to early Phase 2 proof-of-concept stage. No drugs have completed a successful Phase 2b efficacy trial other than larazotide.

Ulcerative colitis drug development has historically been primarily focused on the moderate-to-severe UC population with little investment and research and development in mild-to-moderate UC, which is the majority of the patient populations. Current treatments for mild-to-moderate UC include the mesalamine reformulations that are pictured in Figure 15 below and described above under the heading "History of Drug Development in Mild to Moderate Ulcerative Colitis," as well as Lialda, Pentasa, Asacol HD and Apriso, Valeant/Salix's Uceris (oral MMX-formulated budesonide; a corticosteroid) and 5-mercaptopurine (severe side effects). Eventually, half of the mild-to-moderate UC patients progress from mesalamine to the more expensive biologics, which creates a significant potential market opportunity for any drug that is more effective than mesalamine and less expensive than the biologics.

Figure 15: Other than various reformulations of mesalamine which have been used for the past several decades, no new drugs have been approved for mild-to-moderate UC

Government Regulations

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of drugs, such as those we are developing. Along with third-party contractors, we will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Government Regulation of Drugs

The process required by the FDA before drug product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's current Good Laboratory Practices, or GLP, regulation;
- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee for each clinical site before a clinical trial can begin;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed product candidate for its intended purpose;
- preparation of and submission to the FDA of a New Drug Application, or NDA, after completion of all required clinical trials;

- a determination by the FDA within 60 days of its receipt of a NDA to file the application for review;

- satisfactory completion of an FDA Advisory Committee review, if applicable;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practices, or cGMP, and to assure that the facilities, methods and controls are adequate to preserve the product's continued safety, purity and potency, and of selected clinical investigational sites to assess compliance with current Good Clinical Practices, or cGCPs; and

- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States, which must be updated annually and when significant changes are made.

The testing and approval processes require substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent Institutional Review Board, or IRB, for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of NDA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1. The drug product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, the initial human testing is often conducted in patients.

- Phase 2. The drug product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.

- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

- Phase 4. In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be required as a condition to approval of the NDA.

Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the drug characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

NDA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a NDA requesting approval to market the product for one or more indications. The NDA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. The submission of a NDA requires payment of a substantial User Fee to FDA, and the sponsor of an approved NDA is also subject to annual product and establishment user fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

Within 60 days following submission of the application, the FDA reviews an NDA to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any NDA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the NDA must be resubmitted with the additional information. Once a NDA has been filed, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process may be significantly extended by FDA requests for additional information or clarification. The FDA reviews a NDA to determine, among other things, whether a product is safe and effective for the indication being pursued, and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety and effectiveness. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a NDA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a NDA, the FDA will typically inspect one or more clinical sites to assure compliance with cGCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. After the FDA evaluates a NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may request additional information or clarification. The FDA may delay or refuse approval of a NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the NDA with a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA's review and approval of new drugs that meet certain criteria. Specifically, new drug products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. For a fast track product, the FDA may consider sections of the NDA for review on a rolling basis before the complete application is submitted if relevant criteria are met. A fast track designated product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the NDA at six months after the FDA accepts the application for filing. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve an NDA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Products subject to accelerated approval must have associated marketing materials submitted for pre-approval by the FDA's Office of Prescription Drug Promotion during the pre-approval review period. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the product's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the Food and Drug Administration Safety and Innovation Act, or FDASIA, which was enacted and signed into law in 2012, established breakthrough therapy designation. A sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors may request the FDA to designate a breakthrough therapy at the time of or any time after the submission of an IND, but ideally before an end-of-Phase 2 meeting with FDA. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller or more efficient clinical trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough designation also allows the sponsor to file sections of the NDA for review on a rolling basis. We may seek designation as a breakthrough therapy for some or all of our product candidates.

Fast Track designation, priority review and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

Orphan Drug Status

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drug candidates intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that costs of research and development of the drug for the indication can be recovered by sales of the drug in the United States. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Although there may be some increased communication opportunities, orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a drug candidate that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in very limited circumstances, such as if the second applicant demonstrates the clinical superiority of its product or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Orphan drug exclusivity could block the approval of our drug candidates for seven years if a competitor obtains approval of the same product as defined by the FDA or if our drug candidate is determined to be contained within the competitor's product for the same indication or disease.

As in the United States, designation as an orphan drug for the treatment of a specific indication in the European Union, must be made before the application for marketing authorization is made. Orphan drugs in Europe enjoy economic and marketing benefits, including up to 10 years of market exclusivity for the approved indication unless another applicant can show that its product is safer, more effective or otherwise clinically superior to the orphan designated product.

The FDA and foreign regulators expect holders of exclusivity for orphan drugs to assure the availability of sufficient quantities of their orphan drugs to meet the needs of patients. Failure to do so could result in the withdrawal of marketing exclusivity for the orphan drug.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, distribution, and advertising and promotion of the product. After approval, most changes to the approved product labeling, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with GMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may, among other things, halt their clinical trials, require them to recall a product from distribution, or withdraw approval of the NDA.

Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing.

The FDA may withdraw approval of an NDA if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or

- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of drugs and biologics. A company can make only those claims relating to safety and efficacy that are consistent with the FDA approved label and with FDA regulations governing marketing of prescription products. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Other Healthcare Laws and Compliance Requirements

Our sales, promotion, medical education, clinical research and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services and state and local governments. Our promotional and scientific/educational programs and interactions with healthcare professionals must comply with the federal Anti-Kickback Statute, the civil False Claims Act, physician payment transparency laws, privacy laws, security laws, anti-bribery and corruption laws, and additional federal and state laws similar to the foregoing.

The federal Anti-Kickback Statute prohibits, among other things, the knowing and willing, direct or indirect offer, receipt, solicitation or payment of remuneration in exchange for or to induce the referral of patients, including the purchase, order or lease of any good, facility, item or service that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to increased scrutiny and review if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. The government has enforced the federal Anti-Kickback Statute to reach large settlements with healthcare companies based on sham research or consulting and other financial arrangements with physicians. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Many states have similar laws that apply to their state health care programs as well as private payers.

Federal false claims and false statement laws, including the federal civil False Claims Act, or FCA, impose liability on persons and/or entities that, among other things, knowingly present or cause to be presented claims that are false or fraudulent or not provided as claimed for payment or approval by a federal health care program. The FCA has been used to prosecute persons or entities that "cause" the submission of claims for payment that are inaccurate or fraudulent, by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, submitting claims for services not provided as claimed, or submitting claims for services that were provided but not medically necessary. Actions under the FCA may be brought by the Attorney General or as a qui tam action by a private individual, or whistleblower, in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. The federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other illegal sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, certain companies that were found to be in violation of the FCA have been forced to implement extensive corrective action plans, and have often become subject to consent decrees or corporate integrity agreements, restricting the manner in which they conduct their business.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers; knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services; and willfully obstructing a criminal investigation of a healthcare offense. Like the federal Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Given the significant size of actual and potential settlements, it is expected that the federal government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws. Many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payer, in addition to items and services reimbursed under Medicaid and other state programs. To the extent that our products, once commercialized, are sold in a foreign country, we may be subject to similar foreign laws.

There has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposed new reporting requirements on certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, for payments or other transfers of value made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Covered manufacturers are required to collect and report detailed payment data and submit legal attestation to the accuracy of such data to the government each year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Additionally, entities that do not comply with mandatory reporting requirements may be subject to a corporate integrity agreement. Certain states also mandate implementation of commercial compliance programs, impose restrictions on covered manufacturers' marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians and other healthcare professionals.

We may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and their respective implementing regulations impose specified requirements on certain health care providers, plans and clearinghouses (collectively, "covered entities") and their "business associates," relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain states have their own laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other and/or HIPAA in significant ways and may not have the same effect, thus complicating compliance efforts.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to them, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, imprisonment, contractual damages, reputational harm, and diminished profits and future earnings, any of which could adversely affect our ability to operate our business and our financial results.

In addition to the foregoing health care laws, we are also subject to the U.S. Foreign Corrupt Practices Act, or FCPA, and similar worldwide anti-bribery laws, which generally prohibit companies and their intermediaries from making improper payments to government officials or private-sector recipients for the purpose of obtaining or retaining business. We have plans to adopt an anti-corruption policy, which will become effective upon the completion of this transaction, and expect to prepare and implement procedures to ensure compliance with such policy. The anti-corruption policy mandates compliance with the FCPA and similar anti-bribery laws applicable to our business throughout the world. However, we cannot assure you that such a policy or procedures implemented to enforce such a policy will protect us from intentional, reckless or negligent acts committed by our employees, distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Coverage and Reimbursement

Sales of pharmaceutical products depend significantly on the extent to which coverage and adequate reimbursement are provided by third-party payers. Third-party payers include state and federal government health care programs, managed care providers, private health insurers and other organizations. Although we currently believe that third-party payers will provide coverage and reimbursement for our product candidates, if approved, we cannot be certain of this. Third-party payers are increasingly challenging the price, examining the cost-effectiveness, and reducing reimbursement for medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. The U.S. government, state legislatures and foreign governments have continued implementing cost containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. We may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of our products. The product candidates that we develop may not be considered cost-effective and thus may not be covered or sufficiently reimbursed. It is time consuming and expensive for us to seek coverage and reimbursement from third-party payers, as each payer will make its own determination as to whether to cover a product and at what level of reimbursement. Thus, one payer's decision to provide coverage and adequate reimbursement for a product does not assure that another payer will provide coverage or that the reimbursement levels will be adequate. Moreover, a payer's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow them to sell our products on a competitive and profitable basis.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could materially affect our ability to sell our products profitably. Among policy makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

By way of example, in 2010 the Affordable Care Act was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of the Affordable Care Act of importance to our potential drug candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include, among others, the Budget Control Act of 2011, which mandates aggregate reductions to Medicare payments to providers of up to 2% per fiscal year effective in 2013, and, due to subsequent legislative amendments, will remain in effect through 2024, unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

We expect that healthcare reform measures that may be adopted in the future, including the possible repeal and replacement of the Affordable Care Act which the Trump administration has stated is a priority, are unpredictable, and the potential impact on our operations and financial position are uncertain, but may result in more rigorous coverage criteria and lower reimbursement, and place additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Foreign Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our products to the extent we choose to develop or sell any products outside of the United States. The approval process varies from country to country and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement, and privacy, can vary greatly from country to country.

Research and Development Expenses

Private Innovate had research and development expenses of $4.0 million and $1.9 million for the years ended December 31, 2017 and December 31, 2016, respectively.

Employees

Following completion of the Merger, we now have five full-time employees. We also engage consultants to provide services to us, including clinical development, manufacturing support, regulatory support, business development, and general business operational support.

Corporate Information

Private Innovate was incorporated under the laws of North Carolina under the name “GI Therapeutics, Inc.” in 2012 and changed its name to “Innovate Biopharmaceuticals Inc.” when it converted to a Delaware corporation in 2014. In January 2018, Merger Sub merged with and into Private Innovate with Private Innovate surviving as a wholly owned subsidiary of the Company, and the Company changed its name to Innovate Biopharmaceuticals, Inc. Our principal executive offices are located at 8480 Honeycutt Road, Suite 120, Raleigh, NC 27615 and our telephone number is (919) 275-1933. Our corporate website address is *http://www.innovatebiopharma.com*. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to reports filed pursuant to Sections 13(a) and 15(d) of the Exchange Act, will be made available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission, or the SEC. The contents of our website are not incorporated into this Annual Report on Form 10-K and our reference to the URL for our website is intended to be an inactive textual reference only.

This Annual Report on Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

We are an "emerging growth company" as defined in the JOBS Act, and therefore we may take advantage of certain exemptions from various public company reporting requirements. As an "emerging growth company:"

- we will present no more than two years of audited financial statements and no more than two years of related management's discussion and analysis of financial condition and results of operations;
- we will avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- we will provide less extensive disclosure about our executive compensation arrangements; and
- we will not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

However, we have chosen to irrevocably opt out of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards. We will remain an "emerging growth company" for up to five years, although we will cease to be an "emerging growth company" upon the earliest of (1) December 31, 2021, (2) the last day of the first fiscal year in which our annual gross revenues are $1.07 billion or more, (3) the date on which we have, during the previous rolling three-year period, issued more than $1 billion in non-convertible debt securities, and (4) the date on which we are deemed to be a "large accelerated filer" as defined in the Exchange Act.

Item 1A. Risk Factors.

Our business, financial condition and operating results may be affected by a number of factors, including but not limited to those described below. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from our past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations and stock price. The following information should be read in conjunction with Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements and related notes in Part II, Item 8, "Financial Statements and Supplementary Data" of this Annual Report on Form 10-K.

Risks Related to Our Capital Requirements and Financial Condition

We have a limited operating history and have incurred significant losses since inception, and expect that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.

Monster had a limited operating history and had generated significant negative operating cash flows since inception. Private Innovate has also not been profitable since it commenced operations in 2012, and we may never achieve or sustain profitability. As a clinical-stage biopharmaceutical company, we have a limited operating history upon which to evaluate our business and prospects. In addition, we have limited history as an organization and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical industry. Drug development is a highly speculative undertaking and involves a substantial degree of risk. We have not yet obtained any regulatory approvals for any of our product candidates, commercialized any of our product candidates, or generated any revenue from sales of products. We have devoted significant resources to research and development and other expenses related to our ongoing clinical trials and operations, in addition to acquiring product candidates.

Since inception, most of our resources have been dedicated to the acquisition and development of our product candidates, INN-202 (larazotide acetate), INN-108 and INN-329 (secretin). We will require significant additional capital to continue operations and to execute on our current business strategy to develop INN-202 through to regulatory approval and further develop INN-108 and INN-329 for eventually seeking regulatory approval. We cannot estimate with reasonable certainty the actual amounts necessary to successfully complete the development and commercialization of our product candidates and there is no certainty that we will be able to raise the necessary capital on reasonable terms or at all.

Our auditor has expressed substantial doubt about our ability to continue as a going concern.

The audit reports on Monster's financial statements for the years ended December 31, 2017 and 2016 and Private Innovate's financial statements for the years ended December 31, 2017 and 2016 include an explanatory paragraph related to recurring losses from operations and dependence on additional financing to continue as a going concern. Monster and Private Innovate have incurred net losses for the years ended December 31, 2017 and 2016, and had an accumulated deficit of $40.0 million and $19.4 million, respectively, as of December 31, 2017. In view of these matters, our ability to continue as a going concern is dependent upon our ability to raise additional debt or equity financing or enter into strategic partnerships. On January 29, 2018, Private Innovate sold approximately $18.1 million of shares of common stock, or $16.5 million, net of approximately $1.6 million in placement agent fees and $80,000 in non-accountable expense costs. In addition, Private Innovate received approximately $3.0 million in proceeds from a debt financing. We intend to continue to finance our operations through debt or equity financing and/or strategic partnerships. The failure to obtain sufficient financing or strategic partnerships could adversely affect our ability to achieve our business objectives and continue as a going concern.

We will require substantial additional financing to obtain regulatory approval for INN-202 for celiac disease, and for further development of INN-217 (for NASH) INN-108 (for ulcerative colitis) INN-289 (for Crohn's disease) and INN-329 (for magnetic resonance cholangiopancreatography or MRCP), and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development efforts and other operations.

For the years ended December 31, 2017 and 2016, Private Innovate incurred losses from operations of $11.2 million and $5.4 million, respectively, and net cash used in operating activities was $5.1 million and $2.2 million, respectively. At December 31, 2017, Private Innovate had an accumulated deficit of $19.4 million, cash and cash equivalents of $0.4 million, and a working capital deficit of $12.2 million. We expect to continue to incur substantial operating losses for the next several years as we advance our product candidates through clinical development, U.S. and other regional regulatory approvals, and commercialization. No revenue from operations will likely be available until, and unless, one of our product candidates is approved by the FDA or another regulatory agency and successfully marketed, or we enter into an arrangement that provides for licensing revenue or other partnering-related funding, outcomes which we may not achieve on a timely basis, or at all.

Our capital requirements for the foreseeable future will depend in large part on, and could increase significantly as a result of, our expenditures on our development programs. Future expenditures on our development programs are subject to many uncertainties, and will depend on, and could increase significantly as a result of, many factors, including:

- the number, size, complexity, results and timing of our drug development programs;
- the number of clinical and nonclinical studies necessary to demonstrate acceptable evidence of the safety and efficacy of our product candidates;
- the terms of any collaborative or other strategic arrangement that we may establish;
- changes in standards of care which could increase the size and complexity of clinical studies;
- the ability to locate patients to participate in a study given the limited number of patients available for orphan or ultra-orphan indications;
- the number of patients who participate, the rate of enrollment, and the ratio of randomized to evaluable patients in each clinical study;
- the number and location of sites and the rate of site initiation in each study;
- the duration of patient treatment and follow-up;
- the potential for additional safety monitoring or other post-marketing studies that may be requested by regulatory agencies;
- the time and cost to manufacture clinical trial material and commercial product, including process development and scale-up activities, and to conduct stability studies, which can last several years;
- the degree of difficulty and cost involved in securing alternate manufacturers or suppliers of drug product, components or delivery devices, as necessary to meet FDA requirements and/or commercial demand;
- the costs, requirements, timing of, and the ability to, secure regulatory approvals;
- the extent to which we increase our workforce and the costs involved in recruiting, training and incentivizing new employees;
- the costs related to developing, acquiring and/or contracting for sales, marketing and distribution capabilities, supply chain management capabilities, and regulatory compliance capabilities, if we obtain regulatory approval for a product candidate and commercialize it without a partner;

- the costs involved in evaluating competing technologies and market developments or the loss in sales in case of such competition; and

- the costs involved in establishing, enforcing or defending patent claims and other proprietary rights.

In addition, we are obligated to dedicate a portion of our cash flow to payments on our debt, which reduces the amounts available to fund other corporate initiatives. An event of default on our debt could increase and accelerate the amounts due thereunder.

Additional capital may not be available when we need it, on terms that are acceptable to us or at all. If adequate funds are not available to us on a timely basis, we will be required to delay, limit, reduce or terminate development activities, our establishment of sales and marketing, manufacturing or distribution capabilities, or other activities that may be necessary to commercialize our product candidates, conduct preclinical or clinical studies, or other development activities.

If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may be required to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable. If we raise additional capital through public or private equity offerings, or through debt offerings in which the instruments can convert to equity, the ownership interest of our stockholders will be diluted and the terms of any new equity securities may have preferential rights over our common stock. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt or making capital expenditures, or subject to specified financial ratios, any of which could restrict our ability to develop and commercialize our product candidates or operate as a business.

We have not generated any revenue from product sales and may never be profitable.

We have no products approved for commercialization and have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the requisite regulatory approvals necessary to commercialize, one or more of our product candidates.

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, President Trump signed into law new legislation that significantly revises the Internal Revenue Code of 1986, as amended. The newly enacted federal income tax law, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the new federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

Risks Related to Our Business Strategy and Operations

We do not have any products that are approved for commercial sale.

We currently do not have any therapeutic products approved for commercial sale. We have not received, and may not receive within the next several years, if at all, any revenues from the commercialization of our product candidates if approved.

We are substantially dependent upon the clinical, regulatory and commercial success of our five product candidates, INN-202, INN-217, INN-108, INN-289 and INN-329. Clinical drug development involves a lengthy and expensive process with an uncertain outcome; results of earlier studies and trials may not be predictive of future trial results; and our clinical trials may fail to adequately demonstrate to the satisfaction of regulatory authorities the safety and efficacy of our three product candidates.

The success of our business is dependent on our ability to advance the clinical development of INN-202 for the treatment of celiac disease, INN-217 for NASH, INN-108 for the treatment of mild to moderate ulcerative colitis, INN-289 for Crohn’s disease and INN-329 for MRCP. INN-202 has successfully completed Phase 2 trials; however, Phase 3 pivotal studies and long-term safety studies remain to be conducted. INN-108 will be entering into Phase 2 efficacy trials for mild to moderate ulcerative colitis. INN-329 requires additional studies to be performed for completion of Phase 3 trials.

Clinical testing is expensive and can take many years to complete. The outcome of this testing is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not necessarily be predictive of the results of later-stage clinical trials. There is a high failure rate for drugs proceeding through clinical trials, and product candidates in later stages of clinical trials may fail to show the required safety and efficacy despite having progressed through preclinical studies and initial clinical trials. Many companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval for our product candidates.

Because of the developmental nature of our product candidates, we are subject to risks associated with initiating, completing and achieving positive outcomes from our current and future clinical trials, including:

- inability to enroll enough patients in the clinical trials;
- slow implementation, enrollment and completion of the clinical trials;
- low patient compliance and adherence to dosing and reporting requirements, such as incomplete reporting of patient reported outcomes in the clinical trials or missed doses;
- lack of safety and efficacy in the clinical trials;
- delays in the manufacture of supplies for drug components due to delays in formulation, process development, or manufacturing activities;
- requirements for additional nonclinical or clinical studies based on changes to formulation and/or changes to regulatory requirements;
- requirements for additional clinical studies based on inconclusive clinical results or changes in market, standard of care, and/or regulatory requirements;

If we successfully complete the necessary clinical trials for our product candidates, our success will be subject to the risks associated with obtaining regulatory approvals, product launch, and commercialization, including:

- delays during regulatory review and/or requirements for additional CMC, nonclinical, or clinical studies, resulting in increased costs and/or delays in marketing approval and subsequent commercialization of our product candidates in the United States and other markets;
- FDA rejection of our New Drug Application ("NDA") submissions for our product candidates;
- regulatory rejection in the EU, Japan, and other markets;
- inability to consistently manufacture commercial supplies of drug and delivery devices resulting in slowed market development and lower revenue;
- poor commercial sales due to:
    - the ability of our future sales organization or our potential commercialization partners to effectively sell our product candidates;
    - lack of success in educating physicians and patients about the benefits, administration, and use of our product candidates;
    - low patient demand for our product candidates;
    - the availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments for the targeted indications of our product candidates;
    - poor prescription coverage and inadequate reimbursement for our product candidates;
- inability to enforce our intellectual property rights in and to our product candidates; and
- reduction in the safety profile of our product candidates following approval.

Many of these clinical, regulatory and commercial matters are beyond our control and are subject to other risks described elsewhere in this "Risk Factors" section. Accordingly, we cannot provide any assurances that we will be able to advance our product candidates further through final clinical development or obtain regulatory approval of, commercialize or generate significant revenue from them. If we cannot do so, or are significantly delayed in doing so, our business will be materially harmed.

If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop and commercialize our product candidates.

Private Innovate has historically operated with a limited number of employees. Following the completion of the Merger, we now have five full-time employees, including one employee engaged part-time in research and development. Therefore, institutional knowledge is concentrated within a small number of employees. Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. Our future success is highly dependent upon the contributions of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates.

There may be intense competition from other companies and organizations for qualified personnel. Other companies and organizations with which we compete for personnel may have greater financial and other resources and different risk profiles than we do, and a history of successful development and commercialization of their product candidates. Replacing key employees may be difficult and costly; and we may not have other personnel with the capacity to assume all the responsibilities of a key employee upon his or her departure. If we cannot attract and retain skilled personnel, as needed, we may not achieve our development and other goals.

In addition, the success of our business will depend on our ability to develop and maintain relationships with respected service providers and industry-leading consultants and advisers. If we cannot develop and maintain such relationships, as needed, the rate and success at which we can develop and commercialize product candidates may be limited. In addition, our outsourcing strategy, which has included engaging consultants to manage key functional areas, may subject us to scrutiny under labor laws and regulations, which may divert management time and attention and have an adverse effect on our business and financial condition.

Our management team has limited experience managing a public company.

Most members of our management team have limited experience managing a publicly traded company, interacting with public company investors and complying with the increasingly complex laws pertaining to public companies. Our management team may not successfully or efficiently manage our existence as a public company subject to significant regulatory oversight and reporting obligations under the federal securities laws and the continuous scrutiny of securities analysts and investors. These obligations and constituencies require significant attention from our senior management and could divert their attention away from the day-to-day management of our business.

We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal control, which may impair our ability to produce accurate financial statements or prevent fraud.

Monster has determined that it had a material weakness in its internal control over financial reporting as of December 31, 2017 and 2016. In connection with the preparation of Private Innovate's audited financial statements for the year ended December 31, 2017, the independent auditors of Private Innovate also advised that a material weakness exists in Private Innovate's internal controls over financial reporting due to its inability to adequately segregate duties as a result of our limited number of accounting personnel. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the subject company's annual or interim financial statements will not be prevented or detected on a timely basis. We have limited resources to address our internal controls and procedures and rely on consultants to assist us with our financial accounting and compliance obligations. Although we are committed to continuing to improve our internal control processes and intend to implement a plan to remediate this material weakness, we cannot be certain of the effectiveness of such plan or that, in the future, additional material weaknesses or significant deficiencies will not exist or otherwise be discovered. If we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements and prevent fraud. In addition, if we are unable to successfully remediate the material weaknesses in our internal controls or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected and we may be unable to maintain compliance with applicable stock exchange listing requirements.

Our employees, independent contractors and consultants, principal investigators, CROs, CMOs and other vendors, and any future commercial partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors and consultants, principal investigators, clinical research organizations (CROs), CMOs and other vendors, and any future commercial partners may engage in fraudulent conduct or other misconduct. This type of misconduct may include intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with manufacturing standards required by cGMP or our standards, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, and to report financial information or data accurately or disclose unauthorized activities to them. The misconduct of our employees and other of our service providers could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of business ethics and conduct, but it is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity, such as the implementation of a quality system which entails vendor audits by quality experts, may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We do not have, and do not have plans to establish, manufacturing facilities. We completely rely on third parties for the manufacture and supply of our clinical trial drug supplies and, if approved, commercial product materials. The loss of any of these vendors or a vendor's failure to provide us with an adequate supply of clinical trial or commercial product material in a timely manner and on commercially acceptable terms, or at all, could harm our business.

We outsource the manufacture of our product candidates and do not plan to establish our own manufacturing facilities. To manufacture our product candidates, we have made numerous custom modifications at CMOs, making us highly dependent on these CMOs. For clinical and commercial supplies, if approved, we have or plan to have supply agreements with third party CMOs for drug substance and finished drug product. While we have existing supply agreements with third party CMOs, we would need to negotiate agreements for commercial supply with several important CMOs, and we may not be able to reach agreement on acceptable terms. In addition, we rely on these third parties to conduct or assist us in key manufacturing development activities, including qualification of equipment, developing and validating methods, defining critical process parameters, releasing component materials and conducting stability testing, among other things. If these third parties are unable to perform their tasks successfully in a timely manner, whether for technical, financial or other reasons, we may be unable to secure clinical trial material, or commercial supply material if approved, which likely would delay the initiation, conduct or completion of our clinical studies or prevent us from having enough commercial supply material for sale, which would have a material and adverse effect on our business.

Currently, we do not have alternative vendors to back up our primary vendors of clinical trial material or, if approved, commercial supply material. Identification of and discussions with other vendors may be protracted and/or unsuccessful, or these new vendors may be unsuccessful in producing the same results as the current primary vendors producing the material. Therefore, if our primary vendors become unable or unwilling to perform their required activities, we could experience protracted delays or interruptions in the supply of clinical trial material and, ultimately, product for commercial sale, which would materially and adversely affect our development programs, commercial activities, operating results and financial condition. In addition, the FDA or regulatory authorities outside of the United States may require us to have an alternate manufacturer of a drug product before approving it for marketing and sale in the United States or abroad and securing such alternate manufacturer before approval of an NDA could result in considerable additional time and cost prior to approval.

Any new manufacturer or supplier of finished drug product or our component materials, including drug substance and delivery devices, would be required to qualify under applicable regulatory requirements and would need to have sufficient rights under applicable intellectual property laws to the method of manufacturing of such product or ingredients required by us. The FDA or foreign regulatory agency may require us to conduct additional clinical studies, collect stability data and provide additional information concerning any new supplier, or change in a validated manufacturing process, including scaling-up production, before we could distribute products from that manufacturer or supplier or revised process. For example, if we were to engage a third party other than our current CMOs to supply the drug substance or drug product for future clinical trial, or commercial product, the FDA or regulatory authorities outside of the United States may require us to conduct additional clinical and nonclinical studies to ensure comparability of the drug substance or drug product manufactured by our current CMOs to that manufactured by the new supplier.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling-up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, and shortages of qualified personnel. Our product candidates have not been manufactured at the scale we believe will be necessary to maximize their commercial value, and accordingly, we may encounter difficulties in attempting to scale-up production and may not succeed in that effort on a timely basis or at all. In addition, the FDA or other regulatory authorities may impose additional requirements as we scale-up initial production capabilities, which may delay our scale-up activities and/or add expense.

All manufacturers of our clinical trial material and, if approved, commercial product, including drug substance manufacturers, must comply with cGMP requirements enforced by the FDA through its facilities inspection program and applicable requirements of foreign regulatory authorities. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our clinical trial material may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. While we or our representatives generally monitor and audit our manufacturers' systems, we do not have full control over their ongoing compliance with these regulations. And while the responsibility to maintain cGMP compliance is shared between the third-party manufacturer and us, we bear ultimate responsibility for our supply chain and compliance with regulatory standards. Failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay or failure to obtain product approval, product seizure or recall, or withdrawal of product approval.

If our manufacturers encounter any of the aforementioned difficulties or otherwise fail to comply with their contractual obligations or there are delays entering commercial supply agreements due to capital constraints, we may have insufficient quantities of material to support ongoing and/or planned clinical studies or to meet commercial demand, if approved. In addition, any delay or interruption in the supply of materials necessary or useful to manufacture our product candidates could delay the completion of our clinical studies, increase the costs associated with our development programs and, depending upon the period of delay, require us to commence new clinical studies at significant additional expense or terminate the studies completely. Delays or interruptions in the supply of commercial product could result in increased cost of goods sold and lost sales. We cannot provide assurance that manufacturing or quality control problems will not arise in connection with the manufacture of our clinical trial material or commercial product, if approved, or that third-party manufacturers will be able to maintain the necessary governmental licenses and approvals to continue manufacturing such clinical trial material or commercial product, as applicable. In addition, if our products are manufactured entirely or partially outside the United States, we may experience interruptions in supply due to shipping or customs difficulties or regional instability. Furthermore, changes in currency exchange rates, shipping costs and import tariffs could adversely affect our cost of goods sold. Any of the above factors could cause us to delay or suspend anticipated or ongoing trials, regulatory submissions or commercialization of our product candidates, entail higher costs or result in us being unable to effectively commercialize our products. Our dependence upon third parties for the manufacture of our clinical trial material may adversely affect our future costs and our ability to develop and commercialize our product candidates on a timely and competitive basis.

We currently rely significantly on third parties to conduct our nonclinical testing and clinical studies and other aspects of our development programs. If those third parties do not satisfactorily perform their contractual obligations or meet anticipated deadlines, the development of our product candidates could be adversely affected.

We do not currently employ personnel or possess the facilities necessary to conduct many of the activities associated with our programs. We engage consultants, advisors, CROs, and others to assist in the design and conduct of nonclinical and clinical studies of our product candidates, with interpretation of the results of those studies and with regulatory activities, and expect to continue to outsource all or a significant amount of such activities. As a result, many important aspects of our development programs are and will continue to be outside our direct control, and our third-party service providers may not perform their activities as required or expected including the maintenance of GCP, GLP and GMP compliance, which are ultimately our responsibility to ensure. Further, such third parties may not be as committed to the success of our programs as our own employees and, therefore, may not devote the same time, thoughtfulness or creativity to completing projects or problem-solving as our own employees would. To the extent we are unable to successfully manage the performance of third-party service providers, our business may be adversely affected.

The CROs that we engage or may engage to execute our clinical studies play a significant role in the conduct of the studies, including the collection and analysis of study data, and we likely will depend on CROs and clinical investigators to conduct future clinical studies and to assist in analyzing data from completed studies and developing regulatory strategies for our product candidates. Individuals working at the CROs with which we contract, as well as investigators at the sites at which our studies are conducted, are not our employees, and we have limited control over the amount or timing of resources that they devote to their programs. If our CROs, study investigators, and/or third-party sponsors fail to devote sufficient time and resources to studies of our product candidates, if we and/or our CROs do not comply with all GLP and GCP regulatory and contractual requirements, or if their performance is substandard, it may delay commencement and/or completion of these studies, submission of applications for regulatory approval, regulatory approval, and commercialization of our product candidates. Failure of CROs to meet their obligations to us could adversely affect the development of our product candidates.

In addition, the CROs we engage may have relationships with other commercial entities, some of which may compete with us. Through intentional or unintentional means, our competitors may benefit from lessons learned on the project that could ultimately harm our competitive position. Moreover, if a CRO fails to properly, or at all, perform our activities during a clinical study, we may not be able to enter into arrangements with alternative CROs on acceptable terms or in a timely manner, or at all. Switching CROs may increase costs and divert management time and attention. In addition, there likely would be a transition period before a new CRO commences work. These challenges could result in delays in the commencement or completion of our clinical studies, which could materially impact our ability to meet our desired and/or announced development timelines and have a material adverse impact on our business and financial condition.

We may not achieve our projected development goals within the time frames that we have announced.

We have set goals for accomplishing certain objectives material to the successful development of our product candidates. The actual timing of these events may vary due to many factors, including delays or failures in our nonclinical testing, clinical studies and manufacturing and regulatory activities and the uncertainties inherent in the regulatory approval process. From time to time, we create estimates for the completion of enrollment of or announcement of data from clinical studies of our product candidates. However, predicting the rate of enrollment or the time from completion of enrollment to announcement of data for any clinical study requires us to make significant assumptions that may prove to be incorrect. As discussed in other risk factors above, our estimated enrollment rates and the actual rates may differ materially and the time required to complete enrollment of any clinical study may be considerably longer than we estimate. Such delays may adversely affect our business, financial condition and results of operations.

Even if we complete a clinical study with successful results, we may not achieve our projected development goals within the periods we initially anticipate or announce. If a development plan for a product candidate becomes more extensive and costly than anticipated, we may determine that the associated time and cost are not financially justifiable and, as a result, may discontinue development in a particular indication or of the product candidate as a whole. In addition, even if a study did complete with successful results, changes may occur in regulatory requirements or policy during the period of product development and/or regulatory review of an NDA that relate to the data required to be included in NDAs which may require additional studies that may be costly and time consuming. Any of these actions may be viewed negatively, which could adversely impact our business, financial condition and results of operations.

Further, throughout development, we must provide adequate assurance to the FDA and other regulatory authorities that we can consistently develop and produce our product candidates in conformance with GLP, GCP, cGMP, and other regulatory standards. As discussed above, we rely on CMOs for the manufacture of clinical, and future commercial, quantities of our product candidates. If future FDA or other regulatory authority inspections identify cGMP compliance deficiencies at these third-party facilities, production of our clinical trial material or, in the future, commercial product, could be disrupted, causing potentially substantial delay in or failure of development or commercialization of our product candidates.

We currently have limited marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our products, if approved, or generate product revenue.

To commercialize our products, if approved, in the United States and other jurisdictions we seek approvals, we must build our marketing, sales, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our products receive regulatory approval, we expect to market such products in the United States through a focused, specialized sales force, which will be costly and time consuming. We have no prior experience in the marketing and sale of pharmaceutical products and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Outside of the United States, we may consider collaboration arrangements. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our products in certain markets. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products. If we are not successful in commercializing our products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

To establish a sales and marketing infrastructure and expand our manufacturing capabilities, we will need to increase the size of our organization, and we may experience difficulties in managing this growth.

Following completion of the Merger, we now have five full-time employees, including one employee engaged part-time in research and development. As we advance our product candidates through the development process and to commercialization, we will need to continue to expand our development, regulatory, quality, managerial, sales and marketing, operational, finance and other resources to manage our operations and clinical trials, continue our development activities and commercialize our product candidates, if approved. As our operations expand, we expect that we will need to manage additional relationships with various manufacturers and collaborative partners, suppliers and other organizations.

Due to our limited financial resources and our limited experience in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. In addition, the physical expansion of our operations may lead to significant costs and may divert our management and resources. Any inability to manage growth could delay the execution of our development and strategic objectives, or disrupt our operations, which could materially impact our business, revenue and operating results.

Our product candidates may cause undesirable side effects or adverse events, or have other properties that could delay or prevent their clinical development, regulatory approval or commercialization.

As with many pharmaceutical products, undesirable side effects or adverse events caused by our product candidates could interrupt, delay or halt clinical studies and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all indications, and in turn prevent us from commercializing our product candidates. If undesirable side effects occur, they could possibly prevent approval, which would have a material and adverse effect on our business.

If any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we may be required to change the way the product is administered, conduct additional clinical studies or change the labeling of the product;
- regulatory authorities may withdraw approval of the product; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenue from its sale.

Our business and operations would suffer in the event of third-party computer system failures, cyber-attacks on third-party systems or deficiency in our cyber security.

We rely on information technology (IT) systems, including third-party “cloud based” service providers, to keep financial records, maintain laboratory data, clinical data and corporate records, to communicate with staff and external parties, and to operate other critical functions. This includes critical systems such as email, other communication tools, electronic document repositories, and archives. If any of these third-party information technology providers are compromised due to computer viruses, unauthorized access, malware, natural disasters, fire, terrorism, war and telecommunication failures, electrical failures, cyber-attacks or cyber-intrusions over the internet, then sensitive emails or documents could be exposed or deleted. Similarly, we could incur business disruption if our access to the internet is compromised and we are unable to connect with third-party IT providers. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, we rely on those third parties to safeguard important confidential personal data regarding our employees and patients enrolled in our clinical trials. If a disruption event were to occur and cause interruptions in a third-party IT provider’s operations, it could result in a disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and development of our product candidates could be delayed, or could fail.

Risks Related to Drug Development and Commercialization

We depend on the successful completion of clinical studies of our product candidates, and any positive results in prior clinical studies do not ensure that ongoing or future clinical studies will be successful.

Pharmaceutical products are subject to stringent regulatory requirements covering quality, safety and efficacy. The burden of proof is on the manufacturer, such as us, to show with substantial clinical data that the risk/benefit profile for any new drug is favorable. Only after successfully completing extensive pharmaceutical development, nonclinical testing and clinical studies may a product be considered for regulatory approval.

If we license rights to develop our product candidates to independent third parties or otherwise permit such third parties to evaluate our product candidates in clinical studies, we may have limited control over those clinical studies. Any safety or efficacy concern identified in a third-party sponsored study could adversely affect our or another licensee's development of our product candidate and prospects for our regulatory approval, even if the data from that study are subject to varying interpretations and analyses.

There is significant risk that ongoing and future clinical studies of our product candidates are or will be unsuccessful. Negative or inconclusive results could cause the FDA and other regulatory authorities to require us to repeat or conduct additional clinical studies, which could significantly increase the time and expense associated with development of that product candidate or cause us to elect to discontinue one or more clinical programs. Failure to complete a clinical study of a product candidate or an unsuccessful result of a clinical study could have a material adverse effect on our business.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.

Clinical studies are expensive, difficult to design and implement, may take many years to complete, and outcomes are inherently uncertain. A drug product may fail to demonstrate positive results at any stage of testing despite having progressed satisfactorily through nonclinical testing and initial clinical studies. There is significant risk in clinical development where later stage clinical studies are designed and powered based on the analysis of data from earlier studies, with these earlier studies involving a smaller number of patients, and the results of the earlier studies being driven primarily by a subset of responsive patients. In addition, interim results of a clinical study do not necessarily predict final results. Further, clinical study data frequently are susceptible to varying interpretations. Medical professionals and/or regulatory authorities may analyze or weigh study data differently than the sponsor company, resulting in delay or failure to obtain marketing approval for a product candidate. Additionally, the possible lack of standardization across multiple investigative sites may induce variability in the results, which can interfere with the evaluation of treatment effects.

Delays in commencement and completion of clinical studies are common and have many causes. Delays in clinical studies of our product candidates could increase overall development costs and jeopardize our ability to obtain regulatory approval and successfully commercialize any approved products.

Clinical studies may not commence on time or be completed on schedule, if at all. The commencement and completion of clinical studies can be delayed for a variety of reasons, including:

- inability to raise sufficient funding to initiate or to continue a clinical study;
- delays in obtaining regulatory approval to commence a clinical study;
- delays in identifying and reaching agreement on acceptable terms with prospective CROs and clinical study sites and investigators, which agreements can be subject to extensive negotiation and may vary significantly among study sites;
- delays in obtaining regulatory approval in a prospective country;
- delays in obtaining ethics committee approval to conduct a clinical study at a prospective site;
- delays in reaching agreements on acceptable terms with prospective CMOs or other vendors for the production and supply of clinical trial material and, if necessary, drug administration devices, which agreements can be subject to extensive negotiation;

- delays in the production or delivery of sufficient quantities of clinical trial material from our CMOs and other vendors to initiate or continue a clinical study;
- delays due to product candidate recalls as a result of stability failure, excessive product complaints or other failures of the product candidate during its use or testing;
- invalidation of clinical data caused by premature unblinding or integrity issues;
- invalidation of clinical data caused by mixing up of the active drug and placebo through randomization or manufacturing errors;
- delays on the part of our CROs, CMOs and other third-party contractors in developing procedures and protocols or otherwise conducting activities in accordance with applicable policies and procedures and in accordance with agreed upon timelines;
- delays in identifying and hiring or engaging, as applicable, additional employees or consultants to assist in managing clinical study-related activities;
- delays in recruiting and enrolling individuals to participate in a clinical study, which historically can be challenging in orphan diseases;
- delays caused by patients dropping out of a clinical study due to side effects, concurrent disorders, difficulties in adhering to the study protocol, unknown issues related to different patient profiles than in previous studies, or otherwise;
- delays in having patients complete participation in a clinical study, including returning for post-treatment follow-up;
- delays resulting from study sites dropping out of a trial, providing inadequate staff support for the study, problems with shipment of study supplies to clinical sites, or focusing our staff's efforts on enrolling studies that compete for the same patient population;
- suspension of enrollment at a study site or the imposition of a clinical hold by the FDA or other regulatory authority following an inspection of clinical study operations at study sites or finding of a drug-related serious adverse event; and
- delays in quality control/quality assurance procedures necessary for study database lock and analysis of unblinded data.

We may experience difficulties in the enrollment of patients in our clinical trials, which may delay or prevent us from obtaining regulatory approval.

We may not be able to continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In particular, because we are focused on diseases in genomically defined patient populations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates.

Patient enrollment, a critical component to successful completion of a clinical study, is affected by many factors, including:

- the size of the target patient population;
- other ongoing studies competing for the same patient population;
- the eligibility criteria for the clinical trial;
- the design of the clinical study;
- the perceived risks and benefits of the product candidate under study;

- the efforts to facilitate timely enrollment in clinical trials;
- the proximity and availability of clinical trial sites for prospective patients; and
- the ability to monitor patients adequately during and after treatment.

Clinical studies may not begin on time or be completed in the time frames we anticipate. The length of time necessary to successfully complete clinical studies varies significantly and is difficult to predict accurately. We may make statements regarding anticipated timing for completion of enrollment in and/or availability of results from our clinical studies, but such predictions are subject to a number of significant assumptions and actual timing may differ materially for a variety of reasons, including patient enrollment rates, length of time needed to prepare raw study data for analysis and then to review and analyze it, and other factors described above. If we experience delays in the completion of a clinical study, if a clinical study is terminated, or if failure to conduct a study in accordance with regulatory requirements or the study's protocol leads to deficient safety and/or efficacy data, the regulatory approval and/or commercial prospects for our product candidates may be harmed and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical studies likely will increase our development costs. Further, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may ultimately lead to the denial of regulatory approval of a product candidate. Even if we ultimately commercialize our product candidates, the standard of care may have changed or other therapies for the same indications may have been introduced to the market in the interim and may establish a competitive threat to us or may diminish the need for our products.

Clinical studies are very expensive, difficult to design and implement, often take many years to complete, and the outcome is inherently uncertain.

Clinical development of pharmaceutical products for humans is generally very expensive and takes many years to complete. Failures can occur at any stage of clinical testing. We estimate that clinical development of our product candidates will take several additional years to complete, but because of the variety of factors that can affect the design, timing, and outcome of clinical studies, we are unable to estimate the exact funds required to complete research and development, to obtain regulatory approval and to commercialize all of our product candidates. We will need significant additional capital to continue to advance our product candidates pursuant to our current development and commercialization plans.

Failure at any stage of clinical testing is not uncommon and we may encounter problems that would require additional, unplanned studies or cause us to abandon a clinical development program.

In addition, a clinical study may be suspended or terminated by us, an IRB, a data safety monitoring board, the FDA or other regulatory authorities due to a number of factors, including:

- lack of adequate funding to continue the study;
- failure to conduct the study in accordance with regulatory requirements or the study's protocol;
- inspection of clinical study operations or sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues, including adverse side effects; or
- changes in governmental regulations or administrative actions.

Changes in governmental regulations and guidance relating to clinical studies may occur and we may need to amend study protocols to reflect these changes, or we may amend study protocols for other reasons. Amendments may require us to resubmit protocols to IRBs for reexamination and approval or renegotiate terms with CROs, study sites and investigators, all of which may adversely impact the costs or timing of or our ability to successfully complete a trial.

There is significant uncertainty regarding the regulatory approval process for any investigational new drug, substantial further testing and validation of our product candidates and related manufacturing processes may be required, and regulatory approval may be conditioned, delayed or denied, any of which could delay or prevent us from successfully marketing our product candidates and substantially harm our business.

Pharmaceutical products generally are subject to rigorous nonclinical testing and clinical studies and other approval procedures mandated by the FDA and foreign regulatory authorities. Various federal and foreign statutes and regulations also govern or materially influence the manufacturing, safety, labeling, storage, record keeping and marketing of pharmaceutical products. The process of obtaining these approvals and the subsequent compliance with appropriate U.S. and foreign statutes and regulations is time-consuming and requires the expenditure of substantial resources.

We are preparing INN-202, larazotide acetate, for Phase 3 clinical trials, the success of which will be needed for FDA approval to market INN-202 in the United States to treat celiac disease in patients with persistent symptoms while adhering to a gluten free diet. While significant communication with the FDA on the Phase 3 study design has occurred, even if the Phase 3 clinical study meets all of its statistical goals and protocol end points, the FDA may not view the results as robust and convincing and may require additional clinical studies and/or other costly studies, which could require us to expend substantial additional resources and could significantly extend the timeline for clinical development prior to market approval. Additionally, we are required by the FDA to conduct a long-term safety study on INN-202. The results of this study will not be known until a short time prior to potential submission of an NDA for INN-202. If the safety study cannot be completed for technical or other reasons, or provides results that the FDA determines to be concerning, this may cause a delay or failure in obtaining approval for INN-202. We are conducting pre-clinical work for INN-217 in NASH and INN-289 in Crohn's disease to prepare for future clinical proof-of-concept trials.

We are planning Phase 2 clinical trials for INN-108 for mild-to-moderate ulcerative colitis. Concurrently, we may make formulation changes to INN-108 that would simplify the dosing in pediatric patients. While this change is expected by us to reduce studies and/or other documentation requirements, the regulatory agencies may require additional clinical or nonclinical studies prior to approval, even if current clinical studies are deemed successful, which could require us to expend substantial additional resources and significantly extend the timeline for clinical development of INN-108.

We intend to prepare INN-329, secretin, for additional testing in its Phase 3 clinical trial, the success of which will be needed for FDA approval to market INN-329 in the United States for MRCP procedures. While significant communication with the FDA on the Phase 3 study design has occurred in the past, we will be required to initiate communication with the FDA to finalize the study design and to seek its approval for the additional Phase 3 trial design. Even if the Phase 3 clinical study meets all of its statistical goals and protocol end points, the FDA may not view the results as robust and convincing. The FDA may require additional clinical studies and/or other costly studies, which could require us to expend substantial additional resources and could significantly extend the timeline for clinical development prior to market approval. Additionally, we are required by the FDA to conduct a long-term safety study on INN-329. The results of this study will not be known until a short time prior to potential submission of an NDA for INN-329. If the safety study cannot be completed for technical or other reasons, or provides results that the FDA determines to be concerning, this may cause a delay or failure in obtaining approval for INN-329.

Significant uncertainty exists with respect to the regulatory approval process for any investigational new drug, including INN-202, INN-217, INN-108, INN-289 and INN-329. Regardless of any guidance the FDA or foreign regulatory agencies may provide a drug’s sponsor during its development, the FDA or foreign regulatory agencies retain complete discretion in deciding whether to accept an NDA or the equivalent foreign regulatory approval submission for filing or, if accepted, approve an NDA. There are many components to an NDA or marketing authorization application submission in addition to clinical study data. For example, the FDA or foreign regulatory agencies will review the sponsor’s internal systems and processes, as well as those of its CROs, CMOs and other vendors, related to development of its product candidates, including those pertaining to its clinical studies and manufacturing processes. Before accepting an NDA for review or before approving the NDA, the FDA or foreign regulatory agencies may request that we provide additional information that may require significant resources and time to generate and there is no guarantee that its product candidates will be approved for any indication for which we may apply. The FDA or foreign regulatory agencies may choose not to approve an NDA for any of a variety of reasons, including a decision related to the safety or efficacy data, manufacturing controls or systems, or for any other issues that the agency may identify related to the development of its product candidates. Even if one or more Phase 3 clinical studies are successful in providing statistically significant evidence of the efficacy and safety of the investigational drug, the FDA or foreign regulatory agencies may not consider efficacy and safety data from the submitted studies adequate scientific support for a conclusion of effectiveness and/or safety and may require one or more additional Phase 3 or other studies prior to granting marketing approval. If this were to occur, the overall development cost for the product candidate would be substantially greater and our competitors may bring products to market before we do, which could impair our ability to generate revenues from the product candidates, or even seek approval, if blocked by a competitor’s Orphan Drug exclusivity, which would have a material adverse effect on our business, financial condition and results of operations.

Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. For example, a U.S. federal government shut-down or budget sequestration, such as ones that occurred during 2013 and 2018, may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates.

Even if the FDA or foreign regulatory agencies grant approvals for our product candidates, the conditions or scope of the approval(s) may limit successful commercialization of the product candidates and impair our ability to generate substantial sales revenue. The FDA or foreign regulatory agencies may also only grant marketing approval contingent on the performance of costly post-approval nonclinical or clinical studies, or subject to warnings or contraindications that limit commercialization. Additionally, even after granting approval, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, and continued compliance with cGMP, good clinical practices, international conference on harmonization regulations and good laboratory practices, which are regulations and guidelines that are enforced by the FDA or foreign regulatory agencies for all of our clinical development and for any clinical studies that we conduct post-approval. The FDA or foreign regulatory agencies may decide to withdraw approval, add warnings or narrow the approved indications in the product label, or establish risk management programs that could restrict distribution of our products. These actions could result from, among other things, safety concerns, including unexpected side effects or drug-drug interaction problems, or concerns over misuse of a product. If any of these actions were to occur following approval, we may have to discontinue commercialization of the product, limit our sales and marketing efforts, implement risk minimization procedures, and/or conduct post-approval studies, which in turn could result in significant expense and delay or limit our ability to generate sales revenues.

Regulations may be changed prior to submission of an NDA that require higher hurdles than currently anticipated. These may occur as a result of drug scandals, recalls, or a political environment unrelated to our products.

Even if we receive regulatory approval for a product candidate, we may face regulatory difficulties that could materially and adversely affect our business, financial condition and results of operations.

Even if initial regulatory approval is obtained, as a condition to the initial approval the FDA or a foreign regulatory agency may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or marketing surveillance programs, any of which would limit the commercial potential of the product. Our product candidates also will be subject to ongoing FDA requirements related to the manufacturing processes, labeling, packaging, storage, distribution, advertising, promotion, record-keeping and submission of safety and other post-market information regarding the product. For instance, the FDA may require changes to approved drug labels, require post-approval clinical studies and impose distribution and use restrictions on certain drug products. In addition, approved products, manufacturers and manufacturers' facilities are subject to continuing regulatory review and periodic inspections. If previously unknown problems with a product are discovered, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, the FDA may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If one of our CMOs or us fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- impose civil or criminal penalties;
- suspend or terminate any ongoing clinical studies;
- close the facilities of a CMO;
- refuse to approve pending applications or supplements to approved applications;
- suspend or withdraw regulatory approval;
- exclude our product from reimbursement under government healthcare programs, including Medicaid or Medicare;

- impose restrictions or affirmative obligations on our or our CMOs' operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

If any of our product candidates for which we receive regulatory approval fails to achieve significant market acceptance among the medical community, patients or third-party payers, the revenue we generate from our sales will be limited and our business may not be profitable.

Our success will depend in substantial part on the extent to which our product candidates, if approved, are accepted by the medical community and patients and reimbursed by third-party payers, including government payers. We cannot predict with reasonable accuracy whether physicians, patients, healthcare insurers or health maintenance organizations, or the medical community in general, will accept or utilize any of our products, if approved. If our product candidates are approved but do not achieve an adequate level of acceptance by these parties, we may not generate sufficient revenue to become or to remain profitable. In addition, our efforts to educate the medical community and third-party payers regarding the benefits of our products may require significant resources and may never be successful.

The degree of market acceptance with respect to each of our approved products, if any, will depend upon a number of factors, including:

- the safety and efficacy of our product as demonstrated in clinical studies;
- acceptance in the medical and patient communities of our product as a safe and effective treatment;
- the perceived advantages of our product over alternative treatments, including with respect to the incidence and severity of any adverse side effects and the cost of treatment;
- the indications for which our product is approved;
- claims or other information (including limitations or warnings) in our product's approved labeling;
- reimbursement and coverage policies of government and other third-party payers;
- smaller than expected market size due to lack of disease awareness of a rare disease, or the patient population with a specific rare disease being smaller than anticipated;
- availability of alternative treatments;
- pricing and cost-effectiveness of our product relative to alternative treatments;
- inappropriate diagnostic efforts due to limited knowledge and/or resources among clinicians;
- the prevalence of off-label substitution of chemically equivalent products or alternative treatments; and
- the resources we devote to marketing our product and restrictions on promotional claims we can make with respect to the product.

If we determine that a product candidate may not achieve adequate market acceptance or that the potential market size does not justify additional expenditure on the program, we may reduce our expenditures on the development and/or the process of seeking regulatory approval of the product candidate while we evaluate whether and on what timeline to move the program forward.

Even if we receive regulatory approval to market one or more of our product candidates in the United States, we may never receive approval or commercialize our products outside of the United States, which would limit our ability to realize the full commercial potential of our product candidates.

In order to market products outside of the United States, we must establish and comply with the numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. The time required to obtain approval in other countries generally differs from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States, as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

Conversely, even if our product candidates receive approval outside the United States in the future, we may still be unable to meet the FDA requirements necessary for approval in the United States.

We must comply with the U.S. Foreign Corrupt Practices Act and similar foreign anti-corruption laws.

The U.S. Foreign Corrupt Practices Act, to which we are subject, prohibits corporations and individuals from engaging in certain activities to obtain or retain business or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. Other countries, such as the United Kingdom, have similar laws with which we must comply. We face the risk that an employee or agent could be accused of violating one or more of these laws, particularly in geographies where significant overlap exists between local government and healthcare industries. Such an accusation, even if unwarranted, could prove disruptive to our developmental and commercialization efforts.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we intend to focus on developing product candidates for specific indications that we identify as most likely to succeed, in terms of their potential both to gain regulatory approval and to achieve commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or in other indications with greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

Risks Related to Our Intellectual Property

Our success will depend in part on obtaining and maintaining effective patent and other intellectual property protection for our product candidates and proprietary technology.

We rely on patents and other intellectual property to maintain exclusivity for our product candidates. INN-202 and INN-108 are covered by several issued patents in the U.S. as well as patents outside the U.S., with patent applications pending in several jurisdictions. INN-329 is not protected by patents. Intellectual property relating to the INN-202 program is exclusively licensed from Alba Therapeutics Corp. Intellectual property relating to INN-108 program is exclusively licensed from Seachaid Pharmaceuticals Inc. Our success will depend in part on our ability to:

- obtain and maintain patents and other exclusivity with respect to our products;
- prevent third parties from infringing upon our proprietary rights;
- maintain proprietary know-how and trade secrets;
- operate without infringing upon the patents and proprietary rights of others; and
- obtain and maintain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur or if necessary to secure exclusive rights to them, both in the United States and in foreign countries.

The patent and intellectual property positions of biopharmaceutical companies generally are highly uncertain, involve complex legal and factual questions, and have been and continue to be the subject of much litigation. There is no guarantee that we have or will develop or obtain the rights to products or processes that are patentable, that patents will issue from any pending applications or that claims issued will be sufficient to protect the technology we develop or have developed or that is used by us, our CMOs or our other service providers. In addition, any patents that are issued and/or licensed to us may be limited in scope or challenged, invalidated, infringed or circumvented, including by our competitors, and any rights we have under issued and/or licensed patents may not provide competitive advantages to us. If competitors can develop and commercialize technology and products similar to ours, our ability to successfully commercialize our technology and products may be impaired.

Patent applications in the United States are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months. As a result, we cannot be certain that the inventors listed in any patent or patent application owned or licensed by us were the first to conceive of the inventions covered by such patents and patent applications (for U.S. patent applications filed before March 16, 2013), or that such inventors were the first to file patent applications for such inventions outside the United States and, after March 15, 2013, in the United States. In addition, changes in or different interpretations of patent laws in the United States and foreign countries may affect our patent rights and limit the patents we can obtain, which could permit others to use our discoveries or to develop and to commercialize our technology and products without any compensation to us.

We also rely on unpatented know-how and trade secrets and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, through confidentiality agreements with employees, consultants, collaborators and others. We also have invention or patent assignment agreements with our employees and certain consultants. The steps we have taken to protect our proprietary rights, however, may not be adequate to preclude misappropriation of or otherwise protect our proprietary information or prevent infringement of our intellectual property rights, and we may not have adequate remedies for any such misappropriation or infringement. In addition, it is possible that inventions relevant to our business could be developed by a person not bound by an invention assignment agreement with us or independently discovered by a competitor.

We also intend to rely on regulatory exclusivity for protection of our product candidates, if approved for commercial sale. Implementation and enforcement of regulatory exclusivity, which may consist of regulatory data protection and market protection, varies widely from country to country. Failure to qualify for regulatory exclusivity, or failure to obtain or to maintain the extent or duration of such protections that we expect for our product candidates, if approved, could affect our decision on whether to market the products in a particular country or countries or could otherwise have an adverse impact on our revenue or results of operations.

We may rely on trademarks, trade names and brand names to distinguish our products, if approved for commercial sale, from the products of our competitors. However, our trademark applications may not be approved. Third parties may also oppose our trademark applications or otherwise challenge our use of the trademarks, in which case we may expend substantial resources to defend our proposed or approved trademarks and may enter into agreements with third parties that may limit our use of our trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote significant resources to advertising and marketing these new brands. Further, our competitors may infringe our trademarks or we may not have adequate resources to enforce our trademarks.

If we fail to comply with our obligations under any license, collaboration or other agreements, we could lose intellectual property rights that are necessary for developing and commercializing our product candidates.

Our intellectual property relating to the INN-202 program is licensed from Alba Therapeutics Corp. Our intellectual property relating to the INN-108 program is licensed from Seachaid Pharmaceuticals Inc. Our license agreements with Alba and Seachaid impose, and any future licenses or collaboration agreements we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, patent prosecution and enforcement, and other obligations on us. These type of agreements and related obligations are complex and subject to contractual disputes. If we breach any of these imposed obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages or the licensor may have the right to terminate the license, which could result in our loss of the intellectual property rights and us being unable to develop, manufacture and sell drugs that are covered by the licensed technology.

Our success depends on our ability to prevent competitors from duplicating or developing and commercializing equivalent versions of our product candidates, and intellectual property protection may not be sufficient or effective to exclude this competition.

We have patent protection in the United States and other countries to cover the composition of matter, formulation and method of use for INN-202 and INN-108. However, these patents may not provide us with significant competitive advantages, because the validity, scope, term, or enforceability of the patents may be challenged and, if instituted, one or more of the challenges may be successful. Patents may be challenged in the United States under post-grant review proceedings, *inter partes* reexamination, *ex parte* re-examination, or challenged in district court. Any patents issued in foreign jurisdictions may be subjected to comparable proceedings lodged in various foreign patent offices or courts. These proceedings could result in either loss of the patent or loss or reduction in the scope of one or more of the claims of the patent. Even if a patent issues, and is held valid and enforceable, competitors may be able to design around our patent rights, such as by using pre-existing or newly developed technology, in which case competitors may not infringe our issued claims and may be able to market and sell products that compete directly with ours before and after our patents expire.

Further, the INN-202 primary end point is a proprietary Patient Report Outcome measure (CeD PRO) that is protected by copyright. However, copyright protection may not be sufficient to exclude others from developing products that compete with INN-202.

The patent prosecution process is expensive and time-consuming. We and any future licensors and licensees may not apply for or prosecute patents on certain aspects of our product candidates at a reasonable cost, in a timely fashion, or at all. We may not have the right to control the preparation, filing and prosecution of some patent applications related to our product candidates or technologies. As a result, these patents and patent applications may not be prosecuted and enforced in a manner consistent with our best interests. It is also possible that we or any future or present licensors or licensees will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Further, it is possible that defects of form in the preparation or filing of our patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, assignment, term or claim scope. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid or unenforceable. In addition, one or more parties may independently develop similar technologies or methods, duplicate our technologies or methods, or design around the patented aspects of our products, technologies or methods. Any of these circumstances could impair our ability to protect our products, if approved, in ways which may have an adverse impact on our business, financial condition and operating results.

Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in and outside of the United States. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to use our patents to stop others from using or commercializing similar or identical products or technology, or to limit the duration of the patent protection of our technology and drugs. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar to or identical to ours.

Enforcement of intellectual property rights in certain countries outside the United States, including China in particular, has been limited or non-existent. Future enforcement of patents and proprietary rights in many other countries will likely be problematic or unpredictable. Moreover, the issuance of a patent in one country does not assure the issuance of a similar patent in another country. Claim interpretation and infringement laws vary by nation, so the extent of any patent protection is uncertain and may vary in different jurisdictions.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the United States Patent and Trademark Office, or USPTO, and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in decreased patent term or in abandonment or lapse of the patent or patent application, leading to partial or complete loss of patent rights in the relevant jurisdiction.

Third parties may claim that our products, if approved, infringe on their proprietary rights and may challenge the approved use or uses of a product or our patent rights through litigation or administrative proceedings, and defending such actions may be costly and time consuming, divert management attention away from our business, and result in an unfavorable outcome that could have an adverse effect on our business.

Our commercial success depends on our ability and the ability of our CMOs and component suppliers to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are or may be developing products. Because patent applications can take many years to publish and issue, there currently may be pending applications, unknown to us, that may later result in issued patents that our products, product candidates or technologies infringe, or that the process of manufacturing our products or any of our respective component materials, or the component materials themselves, infringe, or that the use of our products, product candidates or technologies infringe.

We, our CMOs and/or our component material suppliers may be exposed to, or threatened with, litigation by third parties alleging that our products, product candidates and/or technologies infringe our patents and/or other intellectual property rights, or that one or more of the processes for manufacturing our products or any of our respective component materials, or the component materials themselves, or the use of our products, product candidates or technologies, infringe our patents and/or other intellectual property rights. If a third-party patent or other intellectual property right is found to cover our products, product candidates, technologies or uses, or any of the underlying manufacturing processes or components, we could be required to pay damages and could be unable to commercialize our products or to use our technologies or methods unless we are able to obtain a license to the patent or intellectual property right. A license may not be available to us in a timely manner or on acceptable terms, or at all. In addition, during litigation, the third-party alleging infringement could obtain a preliminary injunction or other equitable remedy that could prohibit us from making, using, selling or importing our products, technologies or methods.

There generally is a substantial amount of litigation involving patent and other intellectual property rights in the industries in which we operate and the cost of such litigation may be considerable. We can provide no assurance that our product candidates or technologies will not infringe patents or rights owned by others, licenses to which may not be available to us in a timely manner or on acceptable terms, or at all. If a third party claims that we or our CMOs or component material suppliers infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, with or without merit, may be expensive and time consuming to litigate and may divert management's time and attention from our core business;
- substantial damages for infringement, including the potential for treble damages and attorneys' fees, which we may have to pay if it is determined that the product and/or its use at issue infringes or violates the third party's rights;
- a court prohibiting us from selling or licensing the product unless the third-party licenses its intellectual property rights to us, which it may not be required to do;
- if a license is available from the third party, we may have to pay substantial royalties, fees and/or grant cross-licenses to the third party; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial expense and time.

No assurance can be given that patents do not exist, have not been filed, or could not be filed or issued, which contain claims covering our products, product candidates or technology or those of our CMOs or component material suppliers or the use of our products, product candidates or technologies. Because of the large number of patents issued and patent applications filed in the industries in which we operate, there is a risk that third parties may allege they have patent rights encompassing our products, product candidates or technologies, or those of our CMOs or component material suppliers, or uses of our products, product candidates or technologies.

In the future, it may be necessary for us to enforce our proprietary rights, or to determine the scope, validity and unenforceability of other parties' proprietary rights, through litigation or other dispute proceedings, which may be costly and, to the extent we are unsuccessful, adversely affect our rights. In these proceedings, a court or administrative body could determine that our claims, including those related to enforcing patent rights, are not valid or that an alleged infringer has not infringed our rights. The uncertainty resulting from the mere institution and continuation of any patent- or other proprietary rights-related litigation or interference proceeding could have a material and adverse effect on our business prospects, operating results and financial condition.

Risks Related to Our Industry

We are subject to uncertainty relating to healthcare reform measures and reimbursement policies that, if not favorable to our products, could hinder or prevent our products' commercial success, if any of our product candidates are approved.

The unavailability or inadequacy of third-party payer coverage and reimbursement could negatively affect the market acceptance of our product candidates and the future revenues we may expect to receive from our products. The commercial success of our product candidates, if approved, will depend in part on the extent to which the costs of such products will be covered by third-party payers, such as government health programs, commercial insurance and other organizations. Third-party payers are increasingly challenging the prices and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payers do not consider our products to be cost-effective compared to other therapies, we may not obtain coverage for our products after approval as a benefit under the third-party payers' plans or, even if we do, the level of coverage or payment may not be sufficient to allow us to sell our products on a profitable basis.

Significant uncertainty exists as to the reimbursement status for newly approved drug products, including coding, coverage and payment. There is no uniform policy requirement for coverage and reimbursement for drug products among third-party payers in the United States; therefore coverage and reimbursement for drug products can differ significantly from payer to payer. The coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate payment will be applied consistently or obtained. The process for determining whether a payer will cover and how much it will reimburse a product may be separate from the process of seeking approval of the product or for setting the price of the product. Even if reimbursement is provided, market acceptance of our products may be adversely affected if the amount of payment for our products proves to be unprofitable for healthcare providers or less profitable than alternative treatments or if administrative burdens make our products less desirable to use. Third-party payer reimbursement to providers of our products, if approved, may be subject to a bundled payment that also includes the procedure of administering our products or third-party payers may require providers to perform additional patient testing to justify the use of our products. To the extent there is no separate payment for our product(s), there may be further uncertainty as to the adequacy of reimbursement amounts.

The continuing efforts of governments, private insurance companies, and other organizations to contain or to reduce costs of healthcare may adversely affect:

- our ability to set an appropriate price for our products;
- the rate and scope of adoption of our products by healthcare providers;
- our ability to generate revenue or achieve or maintain profitability;
- the future revenue and profitability of our potential customers, suppliers and collaborators; and
- our access to additional capital.

Our ability to successfully commercialize our products will depend in part on the extent to which governmental authorities, private health insurers and other organizations establish what we believe are appropriate coverage and reimbursement for our products. The containment of healthcare costs has become a priority of federal, state and foreign governments and the prices of drug products have been a focus in this effort. For example, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs, and the Trump administration has stated that reducing drug pricing is a priority. We expect that federal, state and local governments in the United States, as well as governments in other countries, will continue to consider legislation directed at lowering the total cost of healthcare. In addition, in certain foreign markets, the pricing of drug products is subject to government control and reimbursement may in some cases be unavailable or insufficient. It is uncertain whether and how future legislation, whether domestic or abroad, could affect prospects for our product candidates or what actions governmental or private payers for healthcare treatment and services may take in response to any such healthcare reform proposals or legislation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, may prevent or limit our ability to generate revenue, attain profitability or commercialize our product candidates, especially in light of our plans to price our product candidates at a high level.

Furthermore, we expect that the U.S. Congress will again attempt to pass reform measures that may be adopted in the future, including the possible repeal and replacement of the Affordable Care Act, which the Trump administration has stated is a priority. These potential courses of action are unpredictable, and the potential impact of new legislation on our operations and financial position is uncertain, but may result in more rigorous coverage criteria, lower reimbursement, and additional downward pressure on the price we may receive for an approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products, if approved.

We expect competition in the marketplace for our product candidates, should any of them receive regulatory approval.

Larazotide acetate has issued patents for composition of matter, method of use and its formulation in the United States, our primary targeted market. INN-202 has either been issued patents or is prosecuting patent applications in numerous countries outside the United States. The barrier to entry for any company developing larazotide acetate for celiac disease is very high. We believe that INN-202 is the first drug entering into Phase 3 clinical trials for celiac disease. Additionally, if larazotide acetate is the first drug granted FDA approval for celiac disease, competitors may need to license or to seek approval from us for the usage of our CeD-PRO as an endpoint in subsequent celiac disease trials.

We have received Orphan Drug Designation from the FDA for INN-108 for pediatric ulcerative colitis. Orphan Drug Designation will provide market exclusivity in the U.S. for seven years, but only if (1) INN-108 receives market approval before a competitor using the same active compound for the same indication, (2) we are able to produce sufficient supply to meet demand in the marketplace, and (3) another product with the same active ingredient(s) is not deemed clinically superior.

INN-329, secretin, has received Orphan Drug Designation from the FDA. Orphan Drug Designation will provide market exclusivity in the U.S. for seven years, but only if (1) INN-329 receives market approval before a competitor using a similar peptide for the same indication, (2) we are able to produce sufficient supply to meet demand in the marketplace, and (3) another product with the same active ingredient is not deemed clinically superior.

The industries in which we operate are highly competitive and subject to rapid and significant changes. Developments by others may render potential application of any of our product candidates in a particular indication obsolete or noncompetitive, even prior to completion of our development and approval for that indication.

If successfully developed and approved, we expect our product candidates will face competition. We may not be able to compete successfully against organizations with competitive products, particularly large pharmaceutical companies. Many of our potential competitors have significantly greater financial, technical and human resources than we do, and may be better equipped to develop, manufacture, market and distribute products. Many of these companies operate large, well-funded research, development and commercialization programs, have extensive experience in nonclinical and clinical studies, obtaining FDA and other regulatory approvals and manufacturing and marketing products, and have multiple products that have been approved or are in late-stage development. These advantages may enable them to receive approval from the FDA or any foreign regulatory agency before us and prevent us from competing due to their orphan drug protections. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and biotechnology companies. Furthermore, heightened awareness on the part of academic institutions, government agencies and other public and private research organizations of the potential commercial value of their inventions have led them to actively seek to commercialize the technologies they develop, which increases competition for investment in our programs. Competitive products may be more effective, easier to dose, or more effectively marketed and sold, which would have a material adverse effect on our ability to generate revenue.

We face potential product liability exposures, and if successful claims are brought against us, we may incur substantial liability for a product or product candidate and may have to limit its commercialization. In the future, we anticipate that we will need to obtain additional or increased product liability insurance coverage, and we are uncertain whether such increased or additional insurance coverage can be obtained on commercially reasonable terms, if at all.

Our business (in particular, the use of our product candidates in clinical studies and the sale of any products for which we obtain marketing approval) will expose us to product liability risks. Product liability claims may be brought against us by patients, healthcare providers, pharmaceutical companies or others selling or involved in the use of our products. If we cannot successfully defend ourselves against any such claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- significant costs of related litigation;

- decreased demand for our products and loss of revenue;

- impairment of our business reputation;
- a “clinical hold,” suspension or termination of a clinical study or amendments to a study design;
- delays in enrolling patients to participate in our clinical studies;
- withdrawal of clinical study participants;
- substantial monetary awards to patients or other claimants; and
- the inability to commercialize our products and product candidates.

We maintain limited product liability insurance for our clinical studies, and our insurance coverage may not reimburse us or may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

We expect that we will expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates, but we may be unable to obtain product liability insurance on commercially acceptable terms or may not be able to maintain such insurance at a reasonable cost or in sufficient amounts to protect us against potential losses. Large judgments have been awarded in class action lawsuits based on drug products that had unanticipated side effects. A successful product liability claim or series of claims brought against us, if judgments exceed our insurance coverage, could materially decrease our cash and adversely affect our business.

Risks Related to Our Common Stock

The market price of our common stock is likely to be volatile.

The stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. For example, since our stock began trading under the symbol “INNT” on January 29, 2018 through March 12, 2018, the closing price thereof has ranged from a low of $3.52 per share to a high of $19.00 per share. The market price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including:

- regulatory or legal developments in the United States and foreign countries;
- results from or delays in clinical trials of our product candidates;
- announcements of regulatory approval or disapproval of INN-202 (for celiac disease), INN-108 (for ulcerative colitis), INN-329 (for magnetic resonance cholangiopancreatography or MRCP) or any future product candidates;
- commercialization of our product candidates;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- introductions and announcements of new products by us, any commercialization partners or our competitors, and the timing of these introductions and announcements;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- announcements by us or our competitors of significant acquisitions, licenses, strategic partnerships, joint ventures or capital commitments;
- market conditions in the pharmaceutical and biopharmaceutical sectors and issuance of securities analysts’ reports or recommendations;

- actual or anticipated quarterly variations in our results of operations or those of our future competitors;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- sales of substantial amounts of our stock by insiders and large stockholders, or the expectation that such sales might occur;
- general economic, industry and market conditions;
- additions or departures of key personnel;
- intellectual property, product liability or other litigation against us;
- expiration or termination of our potential relationships with strategic partners; and
- the other factors described in this section entitled “Risk Factors.”

If securities or industry analysts do not publish research or publish unfavorable research about our business, our common stock price and trading volume could decline.

Equity research analysts do not currently provide research coverage of our common stock. In particular, as a smaller company, it may be difficult for us to attract the interest of equity research analysts. A lack of research coverage may adversely affect the liquidity of and market price of our common stock. To the extent we obtain equity research analyst coverage, we will not have any control of the analysts or the content and opinions included in their reports. The market price of our stock could decline if one or more equity research analysts begin coverage of our common stock and downgrade our common stock or issue other unfavorable commentary or research on us. If one or more equity research analysts ceases coverage of us in the future, or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause the market price of our common stock or trading volume to decline.

Sales of substantial amounts of our common stock in the public markets, or the perception that such sales might occur, could cause the market price of our common stock to drop significantly, even if our business is doing well.

If our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock that are eligible for sale in the public market, in some cases subject to compliance with the requirements of Rule 144, the trading price of our common stock could decline significantly. As of March 9, 2018, we had approximately 25.7 million shares of common stock outstanding and exercisable warrants to purchase approximately 2.2 million shares of common stock outstanding. We have agreed to register approximately 11.9 million shares and 2.1 million shares issuable upon exercise of outstanding warrants for resale, representing approximately 50.1% of our total outstanding shares of common stock and warrants as of March 9, 2018. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

The issuance of shares upon exercise of our outstanding options and warrants may cause substantial dilution to our existing stockholders and reduce the trading price of our common stock.

We presently have outstanding and exercisable options and warrants that if exercised would result in the issuance of approximately 7.6 million shares of our common stock. The issuance of shares upon exercise of warrants and options may result in dilution to the interests of other stockholders and may reduce the trading price of our common stock.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our certificate of incorporation and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

To the extent that a claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.

If we sell of our common stock in the future, stockholders may experience immediate dilution and, as a result, the market price of our common stock may decline.

We may from time to time issue additional shares of our common stock at a discount from the then-current trading price. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of such common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, the market price of our common stock may decline.

Concentration of ownership of our common stock among our existing principal stockholders may effectively limit the voting power of other stockholders.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock, in aggregate, beneficially own approximately 56.3% of our outstanding common stock. Accordingly, these stockholders, acting together, will continue to be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors and any merger or other significant corporate transactions. These stockholders may therefore delay or prevent a change of control, even if such a change of control would benefit the other stockholders. The significant concentration of stock ownership may adversely affect the market price of our common stock due to investors' perception that conflicts of interest may exist or arise.

A***nti-takeover provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult, which could discourage takeover attempts and lead to management entrenchment, and the market price of our common stock may be lower as a result.***

Certain provisions in our certificate of incorporation and bylaws may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change in control was considered favorable by the stockholders. For example, the Board has the authority to issue up to 10,000,000 shares of preferred stock. The Board can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our organizational documents also contain other provisions that could have an anti-takeover effect, including provisions that:

- provide that vacancies on the Board may be filled only by a majority of directors then in office, even though less than a quorum;
- eliminate cumulative voting in the election of directors;
- authorize the Board to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- permit stockholders to only take actions at a duly called annual or special meeting and not by written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings; and
- authorize the Board, by a majority vote, to amend the bylaws.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that certain investors are willing to pay for our stock.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

We have not paid cash dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends in the near future. The payment of dividends on our common stock will depend on earnings, financial condition and other business and economic factors affecting us at such time as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on investment will only occur if our stock price appreciates.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be subject to certain limitations.

We have U.S. federal net operating loss carryforwards, or NOLs, which expire in various years if not utilized. In addition, we have federal research and development credit carryforwards. The federal research and development credit carryforwards expire in various years if not utilized. Under Sections 382 and 383 of Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change NOLs and other pre-change tax attributes, such as research tax credits, to offset its future post-change income and taxes may be limited. In general, an "ownership change" occurs if there is a cumulative change in our ownership by "5% shareholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We have not performed a formal study to determine whether any of our NOLs are subject to these limitations. We have recorded deferred tax assets for our NOLs and research and development credits and have recorded a full valuation allowance against these deferred tax assets. In the event that it is determined that we have in the past experienced additional ownership changes, or if we experience one or more ownership changes as a result of future transactions in our stock, then we may be further limited in our ability to use our NOLs and other tax assets to reduce taxes owed on the net taxable income that we earn in the event that we attain profitability. Any such limitations on the ability to use our NOLs and other tax assets could adversely impact our business, financial condition and operating results in the event that we attain profitability.

We have incurred and will continue to incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices, including maintaining an effective system of internal control over financial reporting.

As a public company in the United States, and increasingly after we are no longer an "emerging growth company," we may incur significant additional legal, accounting and other expenses that Private Innovate did not incur as a private company. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and regulations implemented by the SEC and Nasdaq, may increase our legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with applicable laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

As a public company in the United States, we are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. We are required to disclose any material weaknesses identified by our management in our internal control over financial reporting, and, when we are no longer an "emerging growth company," we will need to provide a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting.

The controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the Securities and Exchange Commission, or SEC, is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We are in the early stages of conforming our internal control procedures to the requirements of Section 404 and we may not be able to complete our evaluation, testing and any required remediation needed to comply with Section 404 in a timely fashion. Our independent registered public accounting firm was not engaged to perform an audit of our internal control over financial reporting for the year ended December 31, 2017, or for any other period. Accordingly, no such opinion will be expressed.

Even after we develop these new procedures, these new controls may become inadequate because of changes in conditions or the degree of compliance with these policies or procedures may deteriorate and material weaknesses in our internal control over financial reporting may be discovered. We may err in the design or operation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there can be no absolute assurance that all control issues have been or will be detected. If we are unable, or are perceived as unable, to produce reliable financial reports due to internal control deficiencies, investors could lose confidence in our reported financial information and operating results, which could result in a negative market reaction.

To fully comply with Section 404, we will need to retain additional employees to supplement our current finance staff, and we may not be able to do so in a timely manner, or at all. In addition, in the process of evaluating our internal control over financial reporting, we expect that certain of our internal control practices will need to be updated to comply with the requirements of Section 404 and the regulations promulgated thereunder, and we may not be able to do so on a timely basis, or at all. In the event that we are not able to demonstrate compliance with Section 404 in a timely manner, or are unable to produce timely or accurate financial statements, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or the stock exchange on which our stock is listed, and investors may lose confidence in our operating results and the price of our common stock could decline. Furthermore, if we are unable to certify that our internal control over financial reporting is effective and in compliance with Section 404, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or stock exchanges, and we could lose investor confidence in the accuracy and completeness of our financial reports, which could hurt our business, the price of our common stock and our ability to access the capital markets.

Being a public company makes it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. These factors could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups, or JOBS, Act enacted in April 2012, and may remain an "emerging growth company" for up to five years following the completion of our initial public offering, although, if we have more than $1.07 billion in annual revenue, we are deemed to be a large accelerated filer under the rules of the SEC, or we issue more than $1.0 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an "emerging growth company" as of the following December 31. For as long as we remain an "emerging growth company," we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not "emerging growth companies." These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "management's discussion and analysis of financial condition and results of operations" disclosure;

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;

- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;

- reduced disclosure obligations regarding executive compensation; and

- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have irrevocably elected not to avail ourselves of this exemption, and as a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies. We cannot predict whether investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the market price of our common stock may be reduced or more volatile.

Item 1B. Unresolved Staff Comments.

Not applicable

Item 2. Properties.

Our main office is located in Raleigh, North Carolina, where we lease approximately 2,480 square feet of office space under a lease that expires on September 30, 2020. The lease contains a two-year renewal option.

We believe that our existing facilities are adequate to support our near-term needs. We believe that suitable alternative space would be available if required in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

We are not currently a party to any legal or governmental regulatory proceedings, nor is our management currently aware of any pending or threatened legal or governmental regulatory proceedings proposed to be initiated against us that would have a material adverse effect on our business, financial condition or operating results. Our industry is characterized by frequent claims and litigation including securities litigation, claims regarding patent and other intellectual property rights and claims for product liability. As a result, in the future, we may be involved in various legal proceedings from time to time.

On September 15, 2017, a putative class action complaint (the “Class Complaint”) was filed in the United States District Court for the Central District of California against Monster, David H. Clarke, Monster’s Chief Executive Officer and a member of Monster’s Board of Directors, Jonathan Clark, Monster’s Interim President and a member of Monster’s Board of Directors, and Robert Machinist, Christopher Milner and Steven Barre, members of Monster’s Board of Directors (Messrs. Clarke, Clark, Machinist, Miner and Barre are hereinafter referred to as the “Individual Defendants”).

The Class Complaint sought class status on behalf of all of Monster’s public shareholders persons and alleged violations by Monster and the Individual Defendants of Sections 14(a) and 20(a) of the Exchange Act and the rules promulgated thereunder, and secondary control person liability against the Individual Defendants under Section 20(a) of the Exchange Act primarily related to the Merger. The Class Complaint sought to enjoin Monster and the Individual Defendants from proceeding with an anticipated stockholder vote on the Merger or consummating the Merger, unless and until Monster disclosed certain alleged material information that the Class Complaint alleged had been omitted from the proxy statement related thereto, or in the event that the Merger was consummated, to recover an unspecified amount of damages resulting from the Individual Defendants’ alleged violations Sections 14(a) and 20(a) of the Exchange Act. The Class Complaint was withdrawn on November 15, 2017.

Item 4. Mine Safety Disclosures.

Not applicable

PART II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Monster's common stock originally began trading on the Nasdaq Capital Market on July 7, 2016, under the trading symbol "MSDI." Prior to July 7, 2016, there was no public market for Monster's common stock. On January 29, 2018, Monster and Private Innovate completed the Merger. In connection with the Merger, Private Innovate became a wholly owned subsidiary of Monster, and we changed Monster's name to Innovate Biopharmaceuticals, Inc. and changed the trading symbol for the common stock to "INNT." As of March 12, 2018, the closing sales price for our common stock as reported on the Nasdaq Capital Market was $19.00 per share. The following table sets forth reported high and low closing bid quotations for the common stock for the fiscal quarters indicated as reported on Nasdaq (as adjusted for the 1-for-10 reverse stock split of our common stock effected immediately after the Merger). The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

	High	Low
Year Ended December 31, 2016:		
Quarter ended September 30, 2016	$ 40.10	$ 16.10
Quarter ended December 31, 2016	$ 21.53	$ 10.40
Year Ended December 31, 2017		
Quarter ended March 31, 2017	$ 21.60	$ 11.70
Quarter ended June 30, 2017	$ 11.70	$ 4.25
Quarter ended September 30, 2017	$ 16.80	$ 5.30
Quarter ended December 31, 2017	$ 10.00	$ 5.59

Holders

As of March 9, 2018, there were approximately 426 holders of record of our common stock. Holders of record are defined as those stockholders whose shares are registered in their names in our stock records and do not include beneficial owners of common stock whose shares are held in the names of brokers, dealers or clearing agencies.

Dividend Policy

We historically have not, and do not anticipate in the future, paying dividends on our common stock. We currently intend to retain any future earnings to finance our operations and the development and growth of our business. The declaration of any future cash dividend, if any, would be at the discretion of our Board of Directors and would depend upon our earnings, if any, our capital requirements and financial position, general economic conditions, and other factors that our Board of Directors consider to be relevant.

Use of Proceeds from Initial Public Offering

On July 7, 2016, the SEC declared Monster's Registration Statement on Form S-1 (File No. 333-207938) (the "Form S-1") effective, which registered a total of 2,875,000 shares of the common stock, including the underwriters' option to purchase 375,000 additional shares (with an aggregate registered offering price of $14,375,000) and warrants to purchase 2,875,000 shares of the common stock, including the underwriters' option to purchase 375,000 additional warrants (with an aggregate registered offering price of $0), together with the shares of common stock underlying the warrants. On July 13, 2016, Monster closed its initial public offering pursuant to the Form S-1, in which it sold an aggregate of 2,025,000 shares of common stock, $0.0001 par value per share, at a price to the public of $4.50 per share, and warrants to purchase 2,025,000 shares of common stock, at a purchase price of $0.01 per warrant, for aggregate gross proceeds of approximately $9.1 million. The offering terminated before all of the securities registered on the Form S-1 had been sold. As a result of the closing of the initial public offering, Monster received net proceeds of approximately $7.1 million (after underwriters' discounts, commissions, and reimbursements totaling approximately $0.6 million and additional offering related costs of approximately $1.5 million). The sole book-running manager was Axiom Capital Management, Inc. None of the underwriting discounts and commissions or other offering expenses were paid directly or indirectly to any of Monster's directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As contemplated in the final prospectus dated July 7, 2016 and filed with the SEC on July 11, 2016, Monster used the net proceeds from the initial public offering as follows: (i) approximately $0.5 million for the repayment of indebtedness, (ii) approximately $0.4 million pursuant to a license agreement and (iii) the remainder for working capital and general corporate purposes. No payments were made by Monster to any of its directors or officers (or their associates) or persons owning ten percent or more of any class of its equity securities or to any other affiliates.

Item 6. Selected Financial Data.

Not applicable

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Important Explanatory Note

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the notes to those financial statements appearing elsewhere in this Annual Report on Form 10-K. As a result of the Merger, our historic business operations ceased, and our going forward operations will be those historically conducted by Private Innovate.

The consolidated financial statements included herein are those of Monster. All references to historical financial results and operations in this Management's Discussion and Analysis, including where we refer to the "Company," refer to the operations of Monster.

In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward-looking statements by using words such as "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "expect," "plan," "indicate," "seek," "should," "would" and similar expressions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors and risks including, but not limited to, those set forth in "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

General

On July 3, 2017, the Company entered into the Merger Agreement with Private Innovate and Merger Sub. On January 29, 2018, the Company completed the Merger with Private Innovate pursuant to the Merger Agreement.

On September 27, 2017, Monster transferred all of its businesses and assets, including all shares of SDJ Technologies, Inc., and those liabilities of the Company not assumed by Innovate in connection with the Merger to MD Holding Co. Inc., a wholly owned subsidiary of the Company. The shares of MD Holding Co., Inc. were subsequently spun off pro rata to holders of Monster's common stock immediately prior to the Merger (the "Spin-Off"). In January 2018, the name of MD Holding Co. Inc. was changed to HLM Holding Co. Inc.

Immediately prior to the effective time of the Merger, Monster effected a reverse stock split at a ratio of one new share for every ten shares of its common stock outstanding. Under the terms of the Merger Agreement, Monster issued shares of its common stock to Innovate's stockholders at an exchange ratio of 0.37686605 of a share of common stock (post reverse stock split) in exchange for each share of Private Innovate common stock outstanding at the Merger. Innovate assumed $1.0 million of the Company's liabilities. Immediately following the Merger, the Company's corporate name was changed to "Innovate Biopharmaceuticals, Inc."

Year 2017 Compared to Year 2016

Results of Operations

Summary of the Year Ended December 31, 2017

- Net sales for 2017 decreased to $1.9 million as compared to $4.1 million for 2016;
- Gross profit for 2017 was a negative $64,000, or (3.4)% of net sales, as compared to $736,000, or 18.1% of net sales, for 2016;
- Operating expenses, as a percentage of net sales, increased to 472.0% for 2017 compared to 164.3% for 2016;
- Net loss attributable to common stockholders for 2017 was $8.8 million, or $9.36 per diluted share, as compared to $6.2 million, or $11.26 per diluted share, for 2016; and
- Cash used in operations for 2017 was $4.0 million, a decrease from $8.4 million used in 2016.

The following table sets forth, for the periods indicated, the percentage that certain items in the statements of operations bear to net sales and the percentage dollar increase (decrease) of such items from year to year.

	Percent of net sales Year ended December 31,	
	2017	2016
Net sales	100%	100%
Cost of goods sold	(103.4)	(81.9)
Gross profit (loss)	(3.4)	18.1
Operating expenses	(472.0)	(164.3)
Operating loss	(475.4)	(146.2)
Interest and finance expense	5.0	20.3
Gain of debt conversion	—	(13.7)
Gain on extinguishment of debt	(10.6)	—
Gain on settlement of customer refund	(48.9)	—
Loss before income taxes	(420.9)	(152.8)
Income tax provision	—	—
Net loss	(420.9)%	(152.8)%

The following discussion explains in greater detail Monster's consolidated operating results and financial condition. This discussion should be read in conjunction with Monster's consolidated financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K.

	Year ended December 31,	
	2017	2016
	(in thousands)	
Net sales	$ 1,883	$ 4,065

Net sales in 2017 decreased approximately 53.7% to $1.9 million from $4.1 million in 2016. Monster began to rapidly transition away from memory product sales beginning in the third quarter of 2016. In addition, working capital constraints impacted Monster's ability to build traction with its action sports camera line. In the fourth quarter of 2017, Monster stopped filling new orders for its action sports cameras as it transitioned away from using the Monster Digital brand.

	Year ended December 31,	
	2017	2016
	(in thousands)	
Cost of goods sold	$ 1,947	$ 3,329
Gross profit (loss)	$ (64)	$ 736
Gross profit margin	(3.4)%	18.1%

Cost of goods sold primarily includes the cost of products purchased from third party manufacturers and sold to customers. Additional packaging and assembly (labor) costs for certain product orders are also a component of costs of goods sold. Cost of goods sold is affected by inventory obsolescence if inventory management is not effective or efficient. Cost of goods sold decreased approximately 41.5% in 2017 to $1.9 million, as compared to $3.3 million in 2016. As a percentage of net sales, cost of goods sold increased to 103.4% in 2017 from 81.9% in 2016. This increase in cost of sales as a percentage of net sales is attributable to selling price reductions offered to certain customers in order to reduce inventory levels. In addition, fixed and semi-variable costs such as warehouse space and personnel become a more significant percentage of sales as net sales decreases. Gross profit decreased to a negative $64,000 in 2017 as compared to $736,000 in 2016.

	Year ended December 31,	
	2017	2016
	(in thousands)	
Selling and marketing	$ 1,428	$ 2,425
General and administrative	4,984	3,984
Trademark Impairment	2,286	—

Selling and marketing expenses relate primarily to salary and other compensation and associated expenses for internal sales and customer relations personnel, advertising, outbound shipping and freight costs, trade shows, royalties under a brand license, and selling commissions. Selling and marketing expense in 2017 decreased approximately $997,000, or 41.1%, to $1.4 million, as compared to $2.4 million for 2016. Selling and marketing expenses, as a percentage of net sales, were 75.8% and 59.7% for the years ended December 31, 2017 and 2016, respectively. The dollar decrease in selling and marketing expense was significantly attributable to the decrease in expenses such as commissions that vary directly with sales.

General and administrative expenses relate primarily to compensation and associated expenses for personnel in general management, information technology, human resources, procurement, planning and finance, as well as outside legal, investor relations, accounting, consulting and other operating expenses. General and administrative expense in 2017 increased by approximately $1.0 million, or 25.1%, to $5.0 million as compared to $4.0 million in 2016. The increase was significantly attributable to approximate increases in professional and legal fees of $182,000, insurance cost of $168,000 and stock-based compensation of $145,000 in the year ended December 31, 2017 as compared to the year ended December 31, 2016.

	Year ended December 31,	
	2017	2016
	(in thousands)	
Research and development	$ 190	$ 270

Research and development expenses consist of compensation and associated costs of employees engaged in research and development projects, as well as materials and equipment used for these projects, and third party compensation for research and development services.

Research and development expenses for 2017 decreased approximately $80,000, or 30%, to $190,000, as compared to $270,000 for 2016. The decrease is most significantly related to decreased personnel and consulting expenses.

	Year ended December 31,	
	2017	2016
	(in thousands)	
Interest and finance expense	$ 93	$ 825
Gain on debt conversion	—	(557)
Gain on extinguishment of debt	(200)	—
Gain on settlement of customer refund	(920)	—

Interest and finance expense includes interest paid or payable for outstanding borrowings, bank fees, purchase order finance fees, interest accrued on convertible debt, amortization of a debt discount that arose as a result of the issuance of warrants with convertible debt, and amortization of debt issuance costs. Debt conversion expense is a non-cash charge for the effect of an induced conversion of debt to equity.

For the year ended December 31, 2017, the Company incurred approximately $6,000 of interest expense related to its credit facility and $82,000 related to interest on convertible notes. For the year ended December 31, 2017, the Company recorded a gain on extinguishment of debt of $200,000 related to the termination and related settlement of its license agreement with Monster, Inc. The Company also recorded a gain on settlement of customer refund of $920,000 related to a settlement agreement that retired an amount owed to a previous customer. For the year ended December 31, 2016, the Company incurred approximately $55,000 of interest expense related to accounts receivable financing and $740,000 in amortization of debt discount and deferred financing costs related to bridge loan financing. For the year ended December 31, 2016, a $557,000 gain on debt conversion resulted from bridge loan accrued interest and deferred financing costs converting to common stock as part of the Company's initial public offering.

	Year ended December 31,	
	2017	2016
	(in thousands)	
Income tax provision	$ —	$ 2

Income tax expense in 2016 consists of minimum state income taxes due in the states in which Monster operated. The Company did not recognize a deferred tax benefit for the operating losses generated in 2017 or prior due to the uncertainty that it would generate taxable income in the future enabling utilization of the benefit.

Financial Condition

Liquidity and Capital Resources

The Company's primary sources of liquidity during the years ended December 31, 2017 and 2016 were cash raised in the Company's initial public offering, cash raised in private placements of preferred stock, common stock and notes payable and an accounts receivable factoring credit facility. In addition, from time to time, the Company obtained short-term, non-interest bearing loans from a related party to complement its working capital needs.

From October 2015 to March 7, 2016, the Company issued $4.1 million of promissory notes. The notes were due and payable on the earlier of one year from the date of issuance or the closing date of the Company's initial public offering and consisted of $3.36 million loaned to the Company and a 22.5% loan origination fee payable on maturity. Amounts lent bore interest at a fixed amount of 15% of principal loaned, regardless of the time that the loan was outstanding. All principal, interest and fees were payable on the due date. Upon the closing of the Company's initial public offering in July 2016, 90% of the outstanding promissory notes totaling $3,024,000 were converted to common stock and the accrued interest and origination fee were waived as part of the conversion. The remaining unconverted $336,000 of promissory notes were paid along with the accrued interest and origination fee attributable to those notes.

From March 2016 through June 2016, the Company issued 2,802,430 shares of Series A Preferred Stock for net proceeds of $2.4 million to fund inventory purchases and working capital and corporate expenses, including personnel expenses and professional fees and expenses associated with the Company's initial public offering. Upon the closing of the Company's initial public offering in July 2016, the preferred shares were converted to common stock.

On July 13, 2016, the Company closed its initial public offering and received net proceeds of $8,151,000.

In November 2016, the Company issued 48,485 shares of common stock in a private placement receiving net proceeds of approximately $672,000.

On July 24, 2017, the Company entered into a Private Placement Engagement Agreement with WestPark Capital, Inc. for the purpose of raising up to $1,150,000 in convertible debt. An aggregate of $540,000 in convertible debt raised in June and July 2017 prior to the consummation of the WestPark Capital Inc. agreement are under the same terms. The promissory notes (the "Notes") bore interest at 15% and were convertible to common stock concurrent with the Merger at the lesser of $7.50 per share or 75% of the average market value of the Company's common stock for the five days preceding the consummation of such Merger. For every $2.50 in Note principal purchased, investors were entitled to receive one warrant, exercisable for five years, to purchase shares of common stock at $20.00. The Company raised $1,346,500 from this financing and, as of December 31, 2017, a total of $1,346,500 in principal of the Notes remained outstanding. Subsequent to December 31, 2017, the Notes converted to common stock concurrent with the Merger on January 29, 2018. As of December 31, 2017 and 2016, a total of $38,000 in principal of the Notes payable that matured in the second quarter of 2015 remains outstanding.

The Company filed Tender Offer Statements with the Securities and Exchange Commission on October 13, 2017, offering the Company's warrant holders the opportunity to purchase one share of common stock for each warrant held at a price of $4.50. The Company filed a definitive Proxy Statement with the Securities and Exchange Commission on October 12, 2017 to obtain shareholder approval for the Tender Offer and such approval was obtained. In November 2017 warrant holders exercised 288,750 warrants and the Company received net proceeds of approximately $1,189,000 after commission and fees.

Subsequent to December 31, 2017, the Company issued additional shares to certain stockholders pursuant in a private placement. In January 2018, the Company issued 82,632 shares in a private placement receiving net proceeds of approximately $275,000.

Immediately prior to the closing of the Merger, accredited investors purchased shares of common stock of Private Innovate in a private placement for gross proceeds of approximately $18.1 million, or $16.5 million, net of approximately $1.5 million in placement agent fees and $80,000 in non-accountable expense costs (the "Equity Issuance"). Additionally, Private Innovate issued five-year warrants to each cash purchaser of common stock, or an aggregate of approximately 1.4 million warrants, with a price per exercise of $3.05 after giving effect to the exchange ratio. Private Innovate also issued 559,508 five-year warrants with an exercise price of $2.54 and 69,909 five-year warrants with an exercise price of $3.18 to the respective placement agents and their affiliates.

On January 29, 2018, Private Innovate entered into a Note Purchase Agreement and Senior Note Payable ("Note") with a lender. The principal amount of the Note is $4.8 million ("Principal"). The Note was issued at a discount of $1.8 million and net of $20,000 for financing costs, for total proceeds of $2.98 million. The Note matures on September 30, 2018 ("Maturity Date"); however, the Maturity Date may be extended at the option of the lender under certain circumstances as outlined in the Note. Interest on the Note accrues starting on the closing date of the Merger at a rate of 12.5% per annum and payments of interest only are due beginning on March 30, 2018 and compound quarterly. Upon the Maturity Date of the Note, Private Innovate is required to pay the lender an amount representing 105% of all outstanding Principal, accrued and unpaid interest, and any unpaid late charges, if applicable. The Note contains redemption features and certain non-financial covenants and penalties to us in the case of certain events of default, as defined in the Note.

We believe that cash on hand as of December 31, 2017, together with the proceeds from the Equity Issuance and the Note, will only provide us with sufficient financial resources to meet our minimum liquidity requirements through December 31, 2018 and to commence, but not complete, our Phase 3 trials for INN-202. Our failure to raise additional capital would therefore have a material adverse impact on our financial condition and our ability to implement our business strategy.

Discussion of Cash Flows

	Year ended December 31,		
	2017	2016	Change
	(in thousands)		
Net cash used in operating activities	$ (4,002)	$ (8,427)	$ 4,425
Net cash used in investing activities	—	—	—
Net cash provided by financing activities	2,975	9,761	(6,786)
Net increase (decrease) in cash	$ (1,027)	$ 1,334	$ (2,361)

Operating Activities

Net cash used in operating activities in the year ended December 31, 2017 was approximately $4.0 million due primarily to a net loss attributable to common stockholders of $8.0 million and reductions in accrued expenses and customer refund. These uses of cash were offset by a reduction in accounts receivable, inventory and prepaid expenses. In addition, there was an offset to the loss of approximately $1.2 million net of non-cash expenses. Net cash used in operating activities in the year ended December 31, 2016 was approximately $8.4 million due primarily to a net loss of $6.2 million and a decrease in accounts payable and accrued expenses of $2.3 million. Additional uses of cash included increases in accounts receivable, inventory and prepaid expenses offset by non-cash expenses that include stock-based compensation and amortization of deferred costs.

Investing Activities

For 2017 and 2016, the Company did not use any cash in investing activities.

Financing Activities

Net cash provided by financing activities in the year ended December 31, 2017 was approximately $3.0 million and was primarily attributable to the issuance of common stock in private placements and warrant exercise and to the issuance of convertible notes. Net cash provided by financing activities in the year ended December 31, 2016 was approximately $9.8 million and was primarily attributable to the Company's initial public offering proceeds as well as the bridge loan financing and preferred and restricted stock issuances during the year.

Debt Instruments

As of December 31, 2017, debt instruments consisted of two convertible notes payable with a total principal amount of $38,000, due in 2015 that remained unpaid and $1,346,500 in convertible promissory notes. Subsequent to December 31, 2017, these convertible notes converted to common stock concurrent with the Merger.

Operating and Capital Expenditure Requirements

We will need to raise additional financing in the future to fund our operations. In order to meet these additional cash requirements, we would likely need to sell additional equity or convertible securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of convertible securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. If we raise additional funds through collaboration and licensing agreements with third parties, we may be required to relinquish valuable rights to our product candidates, technologies or future revenue streams or to grant licenses on terms that may not be favorable to us.

Contractual Obligations and Commitments

The Company had no long term contractual cash obligations at December 31, 2017. Monster rented an executive suite on a month to month basis and obtained an early termination on its warehouse lease effective January 31, 2018.

Off-Balance Sheet Arrangements

The Company did not have any off-balance sheet arrangements, as defined by applicable SEC rules and regulations, as of December 31, 2017.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Monster's management's discussion and analysis of financial condition and results of operations is based on its consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements required Monster to make estimates and judgments that affected the reported amounts of assets, liabilities and expenses. Monster based its estimates on historical experience and on various assumptions that Monster believed to be reasonable under the circumstances. These estimates and assumptions formed the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that were not readily apparent from other sources. Actual results may differ materially from those estimates.

Revenue recognition

Monster's net sales (revenue) were recognized when there was persuasive evidence that an arrangement existed, when delivery had occurred, when the price to the buyer was fixed or determinable and when collectability of the receivable was reasonably assured. These elements were met when title to the products was passed to the buyers, which was generally when product was delivered to the customer and the customer had accepted delivery. Certain customers had limited rights of return and/or were entitled to price adjustments on products held in their inventory. Monster reduced net sales in the period of sale for estimates of product returns, price adjustments and other allowances. Monster's reserve estimates were based upon historical data as well as projections of sales, customer inventories, price adjustments, average selling prices and market conditions. Price protection was calculated on a product by product basis. The objective of price protection was to mitigate returns by providing retailers with credits to ensure maximum consumer sales. Price protection was granted to retailers after they had presented to Monster an affidavit of existing inventory. Actual returns and adjustments could be significantly different from Monster's estimates and provisions, resulting in an adjustment to net sales.

Inventories

Monster's inventory was stated at the lower of cost or net realizable value, with cost being determined on the weighted average cost method of accounting. Monster purchased finished goods and materials to assemble kits in quantities that Monster anticipated would be fully used in the near term. Changes in operating strategy, customer demand, and fluctuations in market values may have limited Monster's ability to effectively utilize all products purchased and could have resulted in finished goods with above-market carrying costs which may have caused losses on sales to customers. Monster closely monitored inventory levels, obsolescence and lower market values compared to costs and, when necessary, reduced the carrying amount of inventory to net realizable value. As of December 31, 2017 and 2016, inventory on hand was comprised primarily of finished goods ready for sale and packaging materials.

Fair value measurements

Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on the assumptions that market participants would use in pricing an asset or liability. Fair value is based on a hierarchy of valuation techniques, which is determined on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. These two types of inputs create a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Quoted prices for identical instruments in active markets.
Level 2: Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.
Level 3: Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

The carrying amount for other financial instruments, which include cash, accounts receivable, accounts payable, notes payable and line of credit, approximate fair value based upon their short term nature and maturity

Accrued Expenses

Monster incurred periodic expenses such as salaries, professional fees, and contract services. An adjusting entry to accrue expenses would be necessary if expenses were incurred prior to them being invoiced. When a vendor's invoice was not received, Monster was required to estimate its accrued expenses. This process involved reviewing quotations and contracts, identifying services that had been performed on behalf of Monster and estimating the level of service performed and the associated cost incurred for the service when they had not yet been invoiced or otherwise notified of the actual cost. The majority of Monster's service providers invoiced monthly in arrears for services performed or when contractual milestones were met. Monster estimated accrued expenses as of each balance sheet date based on facts and circumstances known at that time.

Share-based compensation/Warrants valuation

Monster used the Black-Scholes model to determine the fair value of stock options and stock purchase warrants on the date of grant. The amount of compensation or other expense recognized using the Black-Scholes model required Monster to exercise judgment and make assumptions relating to the factors that determine the fair value of share-based grants. The fair value calculated by this model was a function of several factors, including the grant price, the expected future volatility, the expected term of the option or warrant and the risk-free interest rate correlating to the term of the option or warrant. The expected term was derived using the simplified method provided in Securities and Exchange Commission release Staff Accounting Bulletin No. 110, which averages an awards weighted average vesting period and contractual term for "plain vanilla" share options. The expected volatility was estimated by analyzing the historic volatility of similar public companies. The risk-free rate of return reflects the weighted average interest rate offered for U.S. treasury rates over the expected life of options or warrants. The expected term and expected future volatility required Monster's judgment. In addition, Monster was required to estimate the expected forfeiture rate and only recognize a cost or expense for those stock options or warrants expected to vest.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

See Note 1 of Notes to Consolidated Financial Statements beginning on page F-8 contained elsewhere in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable

Item 8. Financial Statements and Supplementary Data.

The information required by this item appears beginning on page F-1 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2017. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure. Based on such evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2017, our disclosure controls and procedures were not effective as a result of the material weakness in our internal control over financial reporting described below.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-15(f) and 15d-15(f). Internal control over financial reporting is a process to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our financial statements; providing reasonable assurance that receipts and expenditures of our assets are made in accordance with management's authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements would be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our financial statements would be prevented or detected.

In making the assessment of internal control over financial reporting, our management used the criteria issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework (2013)*. Based on that assessment and those criteria, management determined that our internal control over financial reporting was not effective as of December 31, 2017. Monster's management had previously determined that it had a material weakness in Monster's internal control over financial reporting relating to the design and operation of its closing and financial reporting processes. Monster's management had concluded that this material weakness in its internal control over financial reporting was due to the fact that it did not yet have the appropriate number of staff members with an appropriate level of experience and technical expertise to oversee its closing and financial reporting processes. In order to remediate this material weakness, Monster had taken action to formalize certain of its accounting policies and internal controls documentation and to strengthen supervisory reviews by its management; however, as of December 31, 2017, a material weakness in our internal control over financial reporting still existed.

In connection with the Merger, the management of Monster was replaced by the management of Private Innovate. We have limited resources to address our internal controls and procedures and rely on consultants to assist us with our financial accounting and compliance obligations. In connection with the preparation of Private Innovate's audited financial statements for the year ended December 31, 2017, its independent auditors advised management that a material weakness existed in internal controls over financial reporting due to its inability to adequately segregate duties as a result of our limited number of accounting personnel.

Although we are committed to continuing to improve our internal control processes and intend to implement a plan to remediate our material weakness, we cannot be certain of the effectiveness of such plan or that, in the future, additional material weaknesses or significant deficiencies will not exist or otherwise be discovered. If we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements and prevent fraud. In addition, if we are unable to successfully remediate the material weakness in our internal controls or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected and we may be unable to maintain compliance with applicable stock exchange listing requirements.

Our independent registered public accounting firm has not assessed the effectiveness of our internal control over financial reporting and, under the JOBS Act, will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company."

Changes in Internal Control Over Financial Reporting

As of December 31, 2017, there were no material changes in Monster's internal control over financial reporting that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

As previously announced, on March 9, 2018, our Board of Directors appointed June S. Almenoff, M.D., Ph.D, F.A.C.P. as the Company's Chief Operating Officer and Chief Medical Officer. Additional information about Dr. Almenoff can be found elsewhere in this Annual Report on Form 10-K.

In connection with the appointment of Dr. Almenoff, we entered into an executive employment agreement with her (the "Almenoff Agreement"), pursuant to which Dr. Almenoff is entitled to receive an annual base salary of $320,000, subject to periodic adjustment as we may determine. The Almenoff Agreement provides that, subject to approval of our Board of Directors, Dr. Almenoff will receive an initial grant of options to purchase up to 700,000 shares of our common stock, which shares will vest annually over a four year period. Dr. Almenoff is generally eligible to participate in employee benefit and bonus programs established by the Company from time to time that may be applicable to our executives.

If we terminate the Almenoff Agreement other than "for cause," or if Dr. Almenoff terminates the Almenoff Agreement for "Good Reason," the Almenoff Agreement provides that Dr. Almenoff will receive 12 months of her then-current base salary and up to 12 months of continuation of health insurance benefits, provided that Dr. Almenoff executes and does not revoke a release and settlement agreement in a form satisfactory to us.

Dr. Almenoff's employment is also subject to other customary terms and provisions, including provisions relating to confidentiality, nonsolicitation, noncompetition and invention assignment.

The foregoing description of the Almenoff Agreement is not complete and is subject to, and qualified in its entirety by, the full text of the Almenoff Agreement, a copy of which is filed as Exhibit 10.23 to this Annual Report on Form 10-K and is incorporated herein by reference.

There are no family relationships between Dr. Almenoff and any of our directors or executive officers, or any person nominated or chosen to become a director or executive officer. There are no arrangements or understandings between Dr. Almenoff and any other persons pursuant to which she was selected as Chief Operating Officer and Chief Medical Officer. Dr. Almenoff has no direct or indirect material interest in any transaction or currently proposed transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

As previously announced, in connection with the Merger, David Olert, Monster's former Vice President of Finance and Chief Financial Officer, along with the other former Monster officers, resigned from Monster. We did not appoint a successor to Mr. Olert in connection with the completion of the Merger. On March 9, 2018, in connection with the filing of this Annual Report on Form 10-K, we appointed Mr. Madan as our Interim Principal Financial Officer and Interim Principal Accounting Officer, to serve in these roles until we permanently fill these positions.

On March 11, 2018, we entered into amended and restated executive employment agreements with each of our executive officers: Sandeep Laumas, M.D., Christopher Prior, Ph.D. and Mr. Madan. Such agreements are described in "Item 11. Executive Compensation" of this Annual Report on Form 10-K. Such descriptions are not complete and are subject to, and qualified in their entirety by, the full text of such agreements, copies of which are filed as Exhibit 10.25, 10.26 and 10.27 to this Annual Report on Form 10-K and are incorporated herein by reference. In connection with the entry into the amended and restated executive employment agreement with Mr. Madan, we appointed him to the position of Chief Business Officer in addition to his roles of President and director.

On March 12, 2018, we filed a Certificate of Correction with the Secretary of State of Delaware to correct a clerical error. A copy of our Certificate of Incorporation, as amended and corrected, is filed as Exhibit 3.1 to this Annual Report on Form 10-K.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

At the effective time of the Merger, each of Sandeep Laumas, Christopher Prior, Jay Madan, Lorin Johnson, Anna Kazanchyan, Anthony Maida, and Roy Proujansky was appointed to the Board and such individuals constitute our Board as of the date of this Annual Report. Additionally, pursuant to the Merger Agreement, our executive management team changed at the effective time of the Merger by the resignation of the then-serving executive officers of Monster and the appointment of Sandeep Laumas as our Executive Chairman, Christopher Prior as our Chief Executive Officer, and Jay Madan as our President.

The following table sets forth the names, ages and positions of each of our directors and executive officers as of March 13, 2018:

Name	Age	Position(s)
Sandeep Laumas, M.D.	49	Executive Chairman
Christopher Prior, Ph.D.	65	Chief Executive Officer and Director (principal executive officer)
Jay Madan, M.S.	52	President, Chief Business Officer, Interim Principal Financial Officer, Interim Principal Accounting Officer and Director (principal financial officer and principal accounting officer)
June S. Almenoff, M.D., Ph.D., F.A.C.P.	61	Chief Operating Officer and Chief Medical Officer
Lorin K. Johnson, Ph.D.	65	Director
Anna Kazanchyan, M.D.	49	Director
Anthony E. Maida, Ph.D., M.A., M.B.A	65	Director
Roy Proujansky, M.D.	61	Director

Executive Officers

Sandeep Laumas, M.D. Dr. Laumas joined Private Innovate in 2014 as its Executive Chairman and became our Executive Chairman in connection with the completion of the Merger. In August 2007, Dr. Laumas founded Bearing Circle Capital, LP, an investment partnership, and has served as its Managing Director since such time. Dr. Laumas began his career at Goldman Sachs & Co. in 1996 as an equity analyst in the healthcare investment banking division working on mergers, acquisitions and corporate finance transactions before transitioning to the healthcare equity research division. After leaving Goldman Sachs in 2000, Dr. Laumas moved to the buy side as an analyst at Balyasny Asset Management from 2001 to 2003. Dr. Laumas was a Managing Director of North Sound Capital from 2003 to 2007, where he was responsible for the global healthcare investment portfolio. From February 2011 to 2012 he was a member of the board of directors of Super Religare Laboratories Limited, Southeast Asia's largest clinical laboratory service company. Dr. Laumas serves as an independent director on the Board of directors of Bioxcel Therapeutics, Inc. (Nasdaq: BTAI) and also served as a Director of Parkway Holdings Ltd. (acquired by IHH Healthcare for $3 Billion: Singapore: IHH) from May through August 2010. Dr. Laumas received his A.B. in Chemistry from Cornell University in 1990, M.D. from Albany Medical College in 1995 with a research gap year at the Dana-Farber Cancer Institute and completed his medical internship in 1996 from the Yale University School of Medicine.

We believe that Dr. Laumas's prior board service and years of experience investing in the healthcare industry qualifies Dr. Laumas to serve on our Board.

Christopher P. Prior, Ph.D. Dr. Prior joined Private Innovate as its Chief Executive Officer in 2015 and became our Chief Executive Officer in connection with the completion of the Merger. From April 2008 to October 2014, he served as the Chief Executive Officer of Phasebio Pharmaceuticals, Inc., a clinical stage biopharmaceutical company. Prior to that, he founded Principia Pharmaceutical Corporation, a company that develops biopharmaceutical products for chronic diseases, where he served as President, and BioRexis Pharmaceuticals Corporation, a biopharmaceutical company developing diabetes candidates and novel therapeutic agents, where he served as the President and Chief Scientific Officer. During the course of his 30-year career, he has generated more than 25 INDs and achieved four product approvals from the FDA. Dr. Prior received his Bachelor of Science, with honors, in Chemistry from the University of London, and received a Ph.D. in Biochemistry from Columbia University. Dr. Prior also completed a research fellowship at The Rockefeller Medical Institute in New York. Dr. Prior is a member of the New York Academy of Sciences and is the author of numerous publications and patents focused on the development of therapeutics.

We believe that Dr. Prior's role as our Chief Executive Officer and extensive experience as an executive in the biopharmaceutical industry qualifies him to serve on our Board.

Jay P. Madan, M.S. Mr. Madan founded Private Innovate in 2012 and has served as its President and as a member of the board of directors since such time, and he became our President and a member of our Board in connection with the completion of the Merger. In March 2018, Mr. Madan was also appointed as our Chief Business Officer. Prior to founding Private Innovate, Mr. Madan was an independent contractor advising multiple life sciences companies, including Reliance Life Sciences, Millipore, Baxter, Dade Behring and Goodwin. This experience in working across multiple teams led him to develop a global network of healthcare professionals. From July 2007 to November 2008, Mr. Madan served as the VP of Business Development at Reliance Biopharmaceuticals Pvt. Ltd., a part of Reliance Industries Ltd., India's largest conglomerate. While at Reliance and Goodwin, Mr. Madan was focused on the development of their contract manufacturing businesses. Mr. Madan holds a Bachelor of Science degree in Chemical Engineering from University of Mumbai and an M.S. in Chemical Engineering from Washington State University.

We believe that Mr. Madan's role as a co-founder of Innovate and extensive experience in the life sciences and biotech industries qualifies him to serve on our Board.

June S. Almenoff, M.D., Ph.D., F.A.C.P. Dr. Almenoff began serving as our Chief Operating Officer and Chief Medical Officer in March 2018. Prior to Dr. Almenoff's service with our company, beginning in March 2015, Dr. Almenoff, served as an independent biopharma consultant, including serving as a consultant for Innovate beginning in January 2018. From December 2014 until June 2016, Dr. Almenoff served as an executive-in-residence and consultant at Hatteras Venture Partners, a venture capital firm. From March 2010 until October 2014, Dr. Almenoff served as the president, the chief medical officer and a director of Furiex Pharmaceuticals, Inc., a pharmaceutical company acquired by Allergan in 2014. Prior to serving at Furiex, Dr. Almenoff served for 12 years in various senior roles at GlaxoSmithKline ("GSK"), including as vice president in the clinical safety and pharmacovigilance organization at GSK. Prior to joining GSK, Dr. Almenoff was on the faculty of Duke University Medical Center, where she is currently a Consulting Professor of Medicine. Since 2015, Dr. Almenoff has been the Chair of RDD Pharma, a private, GI clinical stage biopharmaceutical company. Dr. Almenoff serves on the board of directors of the pharmaceutical companies Ohr Pharmaceutical, Inc., TiGenix and Brainstorm Cell Therapeutics Inc. She is an author on more than 50 publications. Dr. Almenoff earned a bachelor's degree, cum laude, from Smith College. She graduated from the M.D.-Ph.D. program at Mt. Sinai School of Medicine and completed a residency in internal medicine and a fellowship in infectious diseases at Stanford University Medical Center. She is a board-certified Fellow of the American College of Physicians with 10 years of clinical practice experience.

Non-Employee Directors

Lorin K. Johnson, Ph.D. Dr. Johnson joined our Board in January 2018. He is the founder and Chief Scientist of Glycyx PharmaVentures Ltd., a biopharma investment and development company. In 1989, he co-founded Salix Pharmaceuticals, Inc. (Nasdaq: SLXP), a specialty pharmaceutical company, and held senior leadership positions prior to its $15.8 billion acquisition by Valeant Pharmaceuticals International, Inc. (NYSEA: VRX) in April 2015. Prior to Salix, Dr. Johnson served as Director of Scientific Operations and Chief Scientist at Scios, Inc. (formerly California Biotechnology, Inc). He is a board member of Sigmoid Pharma Ltd., a GI specialty drug delivery company based in Dublin, Ireland. In addition to his career in industry, Dr. Johnson has served as an Assistant Professor of Pathology at Stanford University Medical Center and held academic positions at Stanford University School of Medicine and the University of California, San Francisco. He is the co-author of 75 journal articles and book chapters and is the co-inventor on 18 issued patents. Dr. Johnson holds a Ph.D. from the University of Southern California and was a Postdoctoral Fellow at the University of California, San Francisco.

We believe that Dr. Johnson's extensive experience in the pharmaceutical and life science industries, both as an executive and investor, qualifies him to serve on our Board.

Anna Kazanchyan, M.D. Dr. Kazanchyan joined our Board in January 2018. She founded Saghmos Therapeutics, a company focused on the prevention of contrast-induced acute kidney injury, in September 2016 and serves as its CEO and Chairwoman. Dr. Kazanchyan has served as a member of the board of directors of Foamix Pharmaceuticals (Nasdaq: FOMX) since December 2014 and currently serves on its compensation committee. She is also the founder and Managing Partner since April 2004 of Primary i-Research, LLC, where she provides due diligence to leading healthcare investment funds and evaluates investment prospects of biopharmaceutical companies based on the scientific, clinical, regulatory and commercial outlook for their products. In addition, she has been a strategic advisor to CEOs of biopharmaceutical companies (start-ups to global companies) and has advised companies on matters related to business development, regulatory strategy, marketing and commercial/competitive landscape. From 2014 to 2016, Dr. Kazanchyan served as SVP, Business Development and Product Development at Ovid Therapeutics, Inc., a company focused on rare neurological disorders. Previously, Dr. Kazanchyan was Senior Biotechnology Analyst at Wachovia Securities, and was a member of the #1 and #2 Institutional-Investor ranked Biotechnology Equity Research teams at Goldman Sachs and Citigroup, respectively. She received an M.D. from Harvard Medical School and a B.A. in Biology, summa cum laude, from Clark University.

We believe that Dr. Kazanchyan's 20 years of experience leading and advising companies in the biopharmaceutical and therapeutics industries qualifies her to serve on our Board.

Anthony E. Maida III, Ph.D., M.A., M.B.A. Dr. Maida joined the Board in January 2018. He has wide experience in the biotechnology industry for more than two decades serving as a CEO, member of the board of directors and working with biotechnology investors. From 1992 to September of 1999, Dr. Maida was President and Chief Executive Officer of Jenner Biotherapies, Inc., an immunotherapy company. From 1997 through 2010, Dr. Maida served as Chairman, Founder and Director of BioConsul Drug Development Corporation and Principal of Anthony Maida Consulting International, advising pharmaceutical and investment firms, in the clinical development of therapeutic products and product/company acquisitions. From June 2009 through June 2010, Dr. Maida served as Vice President of Clinical Research and General Manager, Oncology, Worldwide for PharmaNet, Inc., a clinical research organization. Since June 2010, Dr. Maida has served as Senior Vice President, Clinical Research for Northwest Biotherapeutics, Inc., a cancer vaccine company focused on therapy for patients with glioblastoma multiforme and prostate cancer. Dr. Maida has served in a number of executive roles, including President and CEO of Replicon NeuroTherapeutics, Inc. Dr. Maida is currently a member of the Board of Directors and Audit Chair of Spectrum Pharmaceuticals, Inc (Nasdaq GS: SPPI)., Vitality Biopharma, Inc. (OTCQB: VBIO) and was formerly a member of the Board of Directors and Audit Chair of OncoSec Medical Inc. (OTCQB: ONCS). Dr. Maida holds a B.A. in Biology and History, an M.B.A., an M.A. in Toxicology and a Ph.D. in Immunology. He is a member of the American Society of Clinical Oncology, the American Association for Cancer Research, the Society of Neuro-Oncology, the International Society for Biological Therapy of Cancer and the American Chemical Society.

We believe that Dr. Maida's extensive experience as an executive at various biotechnology and biopharmaceutical companies as well as his service on private and public company boards qualifies him to serve on our Board.

Roy Proujansky, M.D. Dr. Proujansky joined our Board in January 2018. He is a pediatric gastroenterologist who since July 2013 has served as the Executive Vice President and Chief Executive of Delaware Valley Operations (DuPont Hospital for Children) for the Nemours Children's Health System, a non-profit children's health organization. Before his current position, Dr. Proujansky served as Executive Vice President for Patient Operations and Chief Operating Officer of Nemours from 2006 to July 2013. From 2000 to 2006, Dr. Proujansky was the Robert L. Brent Professor and Chairman of Pediatrics and Associate Dean for Jefferson Medical College at Thomas Jefferson University. Additionally, from 1998 to 2015, Dr. Proujansky was the co-director or direct supervisor of Nemours Research Programs and has authored 47 original publications and book chapters in the field of pediatric gastroenterology. Dr. Proujansky received an M.D. from Northwestern University, an M.B.A. from the University of Massachusetts at Amherst and a B.S. in Medical Science from Northwestern University.

We believe Dr. Proujansky's extensive knowledge and experience in the field of pediatric gastroenterology qualifies him to serve on our Board.

Composition of Our Board of Directors

Our Board consists of seven directors, and each director's term expires upon the election and qualification of successor directors at the annual meeting of the stockholders to be held in 2018.

There are no family relationships among any of the directors and executive officers.

Director Independence

Our Board has determined that a majority of its directors are independent as defined under Nasdaq listing standards. The Board has also determined that each current member of each of the Audit Committee, the Nominating and Corporate Governance Committee and the Compensation Committee is independent as defined under Nasdaq listing standards and, as applicable, SEC rules. In making this determination, the Board found that none of these directors had a material or other disqualifying relationship with us.

Committees of the Board of Directors

The Board has an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each of these committees is governed by a formal written charter approved by the Board, and a copy of each such charter is available on our website at: http://ir.innovatebiopharma.com/corporate-governance/highlights. However, the reference to our website does not constitute incorporation by reference of the information contained on or available through our website, and you should not consider it to be a part of this Annual Report on Form 10-K.

Audit Committee

The Audit Committee consists of Anthony Maida, Lorin Johnson and Anna Kazanchyan, with Dr. Maida acting as the chair. The primary functions of the Audit Committee include, among other things:

- selecting and retaining, compensating, overseeing and, if necessary, terminating the independent registered public accounting firm to perform audit services and any permissible non-audit services;
- pre-approving all audit and permitted non-audit and tax services provided by any independent registered public accounting firm;
- reviewing and discussing with the independent registered public accounting firm critical accounting policies and practices, alternative treatments of financial information and other material written communications;
- reviewing and discussing with the independent registered public accounting firm and management our annual financial statements and, following completion of the audit, reviewing separately with the independent registered public accounting firm and management any problems or difficulties encountered during the audit;
- recommending that the audited financial statements be included in our Form 10-K and producing the Audit Committee Report required to be included in our proxy statement;
- reviewing any other relevant reports or other financial information prepared by management and directing the independent registered public accounting firm to use its best efforts to perform all review of interim financial information prior to our disclosure of such financial information;
- coordinating our Board's oversight of our internal control over financial reporting and disclosure controls and procedures;
- discussing our policies with respect to risk assessment and risk management, including guidelines and policies to govern the process by which our exposure to risk is handled;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding (i) accounting, internal accounting controls or auditing matters and (ii) the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;

- reviewing and approving, or making recommendations to our Board regarding, our policies and procedures for reviewing and approving or ratifying related person transactions, and reviewing, approving and overseeing any related person transactions;

- monitoring compliance with our Code of Business Conduct and Ethics; and

- performing an annual review and evaluation of the performance of the Audit Committee and an annual review of its charter.

Each member of the Audit Committee satisfies the independence requirements under Nasdaq listing standards and Rule 10A-3(b)(1) of the Exchange Act and is a person who the Board has determined has the requisite financial expertise required under the applicable requirements of Nasdaq. In arriving at this determination, the Board examined each Audit Committee member's scope of experience and the nature of their employment in the corporate finance sector. The Board has also determined that each of Drs. Maida and Kazanchyan qualifies as an "audit committee financial expert" as defined in applicable SEC rules.

Compensation Committee

The Compensation Committee consists of Anna Kazanchyan, Lorin Johnson and Anthony Maida, with Dr. Kazanchyan acting as the chair. The functions of the Compensation Committee include, among other things:

- reviewing and approving, or recommending that our Board approve, the compensation of the chief executive officer and all other executive officers;

- periodically reviewing and making recommendations to our Board with respect to director compensation;

- reviewing and approving, or recommending that our Board approve, incentive compensation plans and equity-based plans;

- if required, reviewing and discussing with management our "Compensation Discussion and Analysis," recommending that such disclosure be included in our Form 10-K or proxy statement and producing the Compensation Committee Report on executive officer compensation to be included in our Form 10-K or proxy statement;

- reviewing and approving, or making recommendations to our Board regarding, any employment agreements and any severance arrangements or plans, including any benefits to be provided in connection with a change in control, for the chief executive officer and other executive officers;

- overseeing the management of risks relating to our executive compensation plans and arrangements; and

- performing an annual review and evaluation of the performance of the Compensation Committee and an annual review of the charter.

Our Board has determined that each current member of the Compensation Committee is independent under Nasdaq listing standards, a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act and an "outside director" as that term is defined in Section 162(m) of the Internal Revenue Code of 1986, as amended.

Nominating and Corporate Governance Committee

The Nominating and Governance Committee currently consists of Lorin Johnson, Anna Kazanchyan and Anthony Maida, with Dr. Johnson acting as the chair. The functions of the Nominating and Corporate Governance Committee include, among other things, the following:

- identifying and screening individuals qualified to become members of our Board;
- recommending the number of members that shall serve on our Board;
- evaluating and reviewing the qualifications and independent of existing and prospective directors;
- selecting and approving the director nominees to be submitted to a stockholder vote at the annual meeting of stockholders;
- developing and recommending to our Board corporate governance guidelines;
- periodically reviewing our Board's leadership structure;
- overseeing the review by our Board, from time to time, of succession planning for senior executives;
- overseeing the evaluation of our Board and its committees;
- performing an annual review and evaluation of the performance of the Nominating and Corporate Governance Committee and an annual review of the charter.

Our Board has determined that each member of the Nominating and Corporate Governance Committee is independent under Nasdaq listing standards.

Our Board may from time to time establish other committees.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our executive officers, directors and persons who beneficially own more than 10% of our common stock to file initial reports of ownership and reports of changes in ownership with the SEC. These persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms that they file.

To our knowledge, based solely on review of the forms furnished to us and written representations that no other reports were required during the fiscal year ended December 31, 2017, we believe that all Section 16(a) filing requirements applicable to the executive officers, directors and persons who beneficially own more than 10% of our common stock were complied with in 2017, except that Steven Barre had two late Form 4 filings, resulting in the failure to timely report two transactions; Jonathan Clark had one late Form 4 filing, resulting in the failure to timely report one transaction; Robert Machinist had two late Form 4 filings, resulting in the failure to timely report two transactions; Christopher Miner had one late Form 4 filing, resulting in the failure to timely report one transaction; and David Olert had two late Form 4 filings, resulting in the failure to timely report two transactions. In addition, David Clarke failed to timely file a Form 3 due in 2016; Jonathan Clark had one late Form 4 filing in 2018, resulting in the failure to timely report one transaction; David Clarke had one late Form 4 filing in 2018, resulting in the failure to timely report 11 transactions from 2016-2018; and David Olert had one late Form 4 filing in 2018, resulting in the failure to timely report one transaction.

Code of Business Ethics and Conduct

We have adopted a Code of Business Ethics and Conduct that applies to our directors, officers (including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions) and other employees. Our Code of Business Ethics and Conduct is available on the "Corporate Governance" page of the "Investors" section of our website, which may be accessed by navigating to http://ir.innovatebiopharma.com/corporate-governance/highlights, and then by clicking on "Code of Ethics Business Conduct." We intend to post on our website and (if required) file on Form 8-K all disclosures that are required by applicable law, the rules of the SEC or the Nasdaq listing standards, concerning any amendment to, or waiver from, our Code of Business Ethics and Conduct. However, the reference to our website does not constitute incorporation by reference of the information contained on or available through our website, and you should not consider it to be a part of this Annual Report on Form 10-K.

Item 11. Executive Compensation

Introductory Note Regarding Presentation of Information

On January 29, 2018, Monster completed the Merger with Private Innovate. At the effective time of the Merger, the management of Monster was replaced with the management of Private Innovate. Accordingly, we have included compensation information both with respect to Monster's "named executive officers" for 2017 and with respect to the executive officers of Private Innovate that would have been "named executive officers" of Private Innovate for 2017 (such executive officers are referred to as Private Innovate's named executive officers). We have also provided compensation disclosure with respect to all directors of Monster that served during 2017 and for those directors of Private Innovate that were appointed to our Board of Directors in connection with the closing of the Merger.

Executive Compensation – Monster

The following table provides information regarding the compensation of our named executive officers, each of whom was an executive officer of Monster.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)	All Other Compensation ($)	Total ($)
David H. Clarke						
Chief Executive Officer and Chairman of the Board	2017	—	—	—	—	—
	2016	—	—	—	—	—
David Olert						
Chief Financial Officer	2017	195,000	—	—	14,129(1)	209,129
	2016	198,596	46,250	—	13,574(1)	258,420
Stephen R. Brownsell (2)						
Executive Vice President	2017	153,769	—	—	20,484(3)	174,253
	2016	40,808	—	—	2,400(3)	43,208
Jonathan Clark (4)						
Interim President and Director	2017	93,949	—	—	30,164(5)	124,113
	2016	55,000	—	—	3,000(5)	58,000

(1) Represents medical and dental insurance premiums.

(2) Mr. Brownsell joined the Company in October 2016.

(3) Represents medical and dental insurance premiums of $10,884 and automobile expense allowance of $9,600 in 2017. Represents automobile expense allowance in 2016.

(4) Mr. Clark became the Interim President of the Company in October 2016.

(5) Represents medical and dental insurance premiums of $19,814, automobile expense allowance of $9,000 and cell phone allowance of $1,350 in 2017. Represents automobile expense allowance in 2016.

Monster 2017 Outstanding Equity Awards at Year-End

The table below summarizes the aggregate stock and option awards held by our named executive officers as of December 31, 2017

Name	Number of securities underlying unexercised options exercisable	Number of securities underlying unexercised options unexercisable	Option exercise price	Option expiration date	Number of shares of stock that have not vested	Market value of shares of stock that have not vested
David Olert	1,683	—	$ 45.00	7/7/2026	—	—

Monster Employment and Severance Agreements

Monster entered into an Executive Employment Agreement with Mr. Olert, its Chief Financial Officer, in June 2016, pursuant to which Mr. Olert was paid a base salary of $195,000. On July 7, 2016, Mr. Olert was granted 2,500 shares of restricted stock under the Monster 2012 Omnibus Incentive Plan as well as 1,683 stock options at a per share price of $45.00. Mr. Olert received an additional 4,500 shares during 2017.

Mr. Olert's Agreement provided that he was eligible to earn a bonus, which was to be determined exclusively by the Monster Board in its sole discretion.

Mr. Olert's agreement further provided that one-third (1/3) of the restricted stock and stock options granted thereunder would vest on each anniversary of the date thereof. Any unvested shares of restricted stock and stock options in the amount proportional to the time held would vest upon any termination of Mr. Olert's employment other than termination of the agreement by Monster for "cause" or due to the voluntary resignation by the executive in the absence of "good reason." Mr. Olert was eligible to receive additional stock options and/or restricted stock from time to time at the sole discretion of the Monster Compensation Committee and the Monster Board.

Mr. Olert was entitled to apply to participate in such executive benefit plans and programs as Monster had from time to time offered or provided to its executives at similar levels, including, but not limited to, any life insurance, health and accident, medical and dental, disability and retirement plans and programs.

In the event of the termination of the agreement by Monster without "cause" or due to the voluntary resignation by Mr. Olert for "good reason," Mr. Olert was entitled to a severance payment equal to 1/3 of his then Base Salary, payable in accordance with Monster's customary payroll practices.

Following the completion of the Merger, we entered into a consulting agreement with Mr. Olert to provide professional and consulting services to us related to the preparation of Monster's financial statements, filings with the Securities and Exchange Commission and other related matters. The term of Mr. Olert's consulting agreement runs through the filing date of this Annual Report on Form 10-K (the "Initial Term") and will automatically renew for successive three-month terms unless otherwise terminated. Mr. Olert is compensated on an hourly basis under the agreement and is eligible for a $10,000 completion bonus for satisfactory service through the Initial Term.

Director Compensation – Monster

Monster issued Mr. Clarke 17,500 and 10,000 shares of its common stock in January 2017 and November 2017, respectively.

Monster's board of directors had a compensation program for its non-employee, independent directors. Each such Monster director received an initial share or stock option grants of up to 1,500 shares.

Executive Compensation – Private Innovate

The following table provides information regarding Private Innovate's named executive officers for the years ended December 31, 2017 and 2016.

Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus[1]	Option Awards[2]	Total
Sandeep Laumas, M.D.					
Executive Chairman	2017	$ 137,000	$ 132,500	$ 282,172	$ 551,672
	2016	$ 18,000[3]	$ 2,100	$ —	$ 20,100
Christopher Prior, Ph.D.					
Chief Executive Officer	2017	$ 172,000	$ 60,000	$ 248,563	480,563
	2016	$ 18,000	$ 2,100	$ 1,250,392	$ 1,270,492
Jay P. Madan					
President	2017	$ 170,000	$ 140,000	$ 269,245	579,245
	2016	$ 30,000[4]	$ 4,500	$ —	$ 34,500

(1) As described below under the heading "Employment Agreements," pursuant to the terms of each executive officer's employment agreement with Private Innovate, bonus payments would be made if Private Innovate reached a specified financial milestone prior to March 15, 2018. During the year ended December 31, 2017, Milestone 1, as defined in the Private Innovate employment agreements was achieved and paid and such amounts are included in bonus compensation in the table herein.

(2) The amounts in the "Option Awards" column reflect the aggregate grant date fair value of stock options granted during the calendar year computed in accordance with the provisions of Accounting Standards Codification (ASC) 718, Compensation — Stock Compensation. The assumptions that Private Innovate used to calculate these amounts are discussed in the notes to the December 31, 2017 and 2016 audited financial statements of Private Innovate included in the Current Report on Form 8-K of Innovate Biopharmaceuticals, Inc. dated March 13, 2018. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

(3) As described below under the heading "Employment Agreements," under the terms of Dr. Laumas's Private Innovate employment agreement, a portion of the amount of the 2016 base salary set forth in the agreement was deferred and would be paid if Private Innovate reached a specified financial milestone prior to March 15, 2017. The milestone was not reached by that date, and the amount in the table reflects the amounts paid in 2016.

(4) As described below under the heading "Employment Agreements," under the terms of Mr. Madan's Private Innovate employment agreement, a portion of the amount of the 2016 base salary set forth in the agreement was deferred and would be paid if Private Innovate reached a specified financial milestone prior to March 15, 2017. The milestone was not reached by that date, and the amount in the table reflects the amounts paid in 2016.

Narrative Disclosure to Summary Compensation Table

The primary elements of compensation for Private Innovate's named executive officers consisted of base salary, bonus and equity-based compensation awards. Private Innovate's named executive officers were also able to participate in employee benefit plans and programs that Private Innovate offered to its other full-time employees on the same basis.

Base Salary

The base salary payable to Private Innovate's named executive officers was intended to provide a fixed component of compensation that reflected the executive's skill set, experience, role and responsibilities.

Bonus

Although Private Innovate did not have a written bonus plan, the board of directors of Private Innovate had the authority, in its discretion, to award bonuses to its executive officers on a case-by-case basis. These awards were structured to reward the executive officers for the successful performance of Private Innovate as a whole and on an individual basis. In addition, as described under the heading "Employment Agreements," each of the executive officers was eligible under the terms of his respective employment agreement to receive a fixed bonus amount based on Private Innovate's achievement of certain financial milestones. The bonus amounts awarded for 2016 performance were on an entirely discretionary basis. The bonus amounts awarded for 2017 included certain discretionary amounts in addition to amounts determined pursuant to such employment agreements.

Equity Awards

Although Private Innovate did not have a formal policy with respect to the grant of equity incentive awards to its executive officers or any formal equity ownership guidelines applicable to them, Private Innovate believed that equity grants provided its executives with a strong link to Private Innovate's long-term performance, created an ownership culture and helped to align the interests of Private Innovate's executives and its stockholders. In addition, Private Innovate believed that equity grants with a time-based vesting feature promoted executive retention by incentivizing executive officers to remain in Private Innovate's employment during the vesting period.

Health, Welfare and Additional Benefits

Each of Private Innovate's named executive officers was eligible to participate in Private Innovate's employee benefit plans and programs, including medical, dental and vision benefits, to the same extent as its other full-time employees, subject to the terms and eligibility requirements of those plans.

2017 Outstanding Equity Awards at Year-End

The following table presents the outstanding equity awards of Private Innovate held as of December 31, 2017 by Private Innovate's named executive officers (as adjusted to give effect to the share exchange that occurred in connection with the Merger).

	Option Awards			
Name	**Number of Securities Underlying Unexercised Options Exercisable**	**Number of Securities Underlying Unexercised Options Unexercisable**	**Option Exercise price**	**Option Expiration date**
Sandeep Laumas, M.D.	41,455	71,604	$ 2.08	3/21/2027
	13,870	85,998	$ 2.34	8/30/2027
Christopher Prior, Ph.D.	1,356,717		$ 0.30	7/1/2026
	522,901	155,457	$ 0.30	7/1/2026
	41,455	71,604	$ 2.08	3/21/2027
	10,468	64,904	$ 2.34	8/31/2027
Jay P. Madan	41,455	71,604	$ 2.08	3/21/2027
	12,562	77,885	$ 2.34	8/30/2027

Employment Agreements

Private Innovate had entered into employment agreements with each of Private Innovate's named executive officers as described below. Each of the agreements described below relates to the information appearing in the tables in this "Item 11. Executive Compensation" of this Annual Report on Form 10-K.

Sandeep Laumas, M.D.

Private Innovate entered into an executive employment agreement with Dr. Laumas in October 2015, which was subsequently amended in February 2016, March 2017 and August 2017.

The agreement provided for an initial base salary of $75,000, which was increased to $111,000 effective July 1, 2016. The agreement provided that the base salary was to be deferred until the time of the Minimum Financial Milestone Event; however, if such Minimum Financial Milestone Event did not occur on or before March 15, 2017, Dr. Laumas agreed to forfeit such base salary for the period of January 1, 2016, through December 31, 2016. The Minimum Financial Milestone Event occurred after March 15, 2017.

Commencing January 1, 2017, $75,000 of Dr. Laumas's annual base salary was subjected to deferral, with such deferral and salary accrual continuing until the Minimum Financial Milestone Event occurred, so long as the Minimum Financial Milestone Event occurred on or prior to March 15, 2018. If the Minimum Financial Milestone Event did not occur on or before March 15, 2018, Dr. Laumas agreed to forfeit such 2017 deferred salary for the period of January 1, 2017, through December 31, 2017. As the Minimum Milestone Event was achieved in April 2017, all deferred 2017 annual base salary was paid.

After the occurrence of the Minimum Milestone Event, Dr. Laumas's annual base salary increased to $150,000 and was not subject to deferral. Upon the occurrence of the Second and Third Financial Milestone Event, Dr. Laumas's annual base salary was to increase to $160,000 and $175,000, respectively. Effective with the consummation of the Equity Issuance in January 2018, the Second and Third Milestone Events were achieved. Upon the occurrence of the Fourth Financial Milestone Event, Dr. Laumas's annual base salary was to increase to $300,000.

The agreement also provided that Dr. Laumas would be eligible to receive a one-time lump sum cash bonus in the amount of $25,000 upon the occurrence of the Minimum Milestone Event, a one-time lump sum cash bonus in the amount of $110,000 upon the occurrence of the Second Financial Milestone Event, a one-time lump sum cash bonus in the appoint of $175,000 upon the occurrence of the Minimum Third Milestone Event, and a one-time lump sum cash bonus in the amount of $175,000 upon the occurrence of the Minimum Fourth Milestone Event. The Minimum Milestone Event was achieved in April 2017 and paid and the Second and Third Milestone Events were achieved effective with the consummation of the Equity Issuance in January 2018. The bonus amounts associated with the Second and Third Milestone Events were included in Private Innovate's accrued liabilities as of December 31, 2017.

For the months of July, August and September 2016, Dr. Laumas was eligible for a discretionary monthly bonus in the amount of $700 per month. If a Minimum Financial Milestone Event had not occurred by March 15, 2017, Dr. Laumas was eligible for a discretionary bonus of $75,000, awarded in Private Innovate's discretion upon the achievement of certain corporate objectives on or before December 31, 2017. This discretionary bonus was awarded and paid during 2017. Dr. Laumas also received a discretionary bonus of $32,500 during 2017 as compensation for his board of director services.

During 2017, Dr. Laumas was also eligible to receive periodic stock or option awards in the discretion of Private Innovate.

Christopher P. Prior, Ph.D.

Private Innovate entered into an executive employment agreement with Dr. Prior in November 2015, which was subsequently amended in February 2016, twice in March 2017, and in August 2017.

Upon the occurrence of the Minimum Financial Milestone Event, Dr. Prior was entitled to an annual base salary of $240,000. Upon the occurrence of the Second and Third Financial Milestone Events, Dr. Prior's annual base salary increased to $260,000 and $300,000, respectively. Effective with the Consummation of the Equity Issuance in January 2018, the Second and Third Milestone Events were achieved. Upon the occurrence of the Fourth Financial Milestone Event, defined as the sale by Private Innovate of its equity securities in a bona fide equity financing or the sale of assets or entry into out-licensing and/or partnering agreements in which Private Innovate receives gross proceeds of not less than $45,000,000 (including proceeds from the Minimum Financial Milestone Event, the Second Milestone Financial Event and the Third Milestone Financial Event), Dr. Prior's annual base salary was to increase to $425,000.

The agreement also provided that Dr. Prior will be eligible to receive a one-time lump sum cash bonus in the amount of $60,000 upon the occurrence of the Minimum Financial Milestone Event, a one-time lump sum cash bonus in the amount of $125,000 upon the occurrence of the Second Financial Milestone Event, a one-time lump sum cash bonus in the appoint of $175,000 upon the occurrence of the Minimum Third Milestone Event, and a one-time lump sum cash bonus in the appoint of $175,000 upon the occurrence of the Minimum Fourth Milestone Event. The Minimum Milestone Event was achieved in April 2017 and paid, and the Second and Third Milestone Events were achieved Effective with the consummation of the Equity Issuance in January 2018. The bonus amounts associated with the Second and Third Milestone Events were included in Private Innovate's other accrued liabilities as of December 31, 2017.

The agreement provided that following the completion of the Minimum Financial Milestone Event, Dr. Prior became eligible for an annual grant of restricted stock for each year of service subject to the completion of certain milestones and the approval of the Innovate Board. Such grants would vest with respect to 25% of the restricted stock on the one year anniversary of the date of grant and thereafter with respect to 75% of the stock over the following three years. Upon a change of control, 100% of the unvested shares of restricted stock would vest.

During 2017, Dr. Prior was also eligible to receive periodic stock or option awards in the discretion of Private Innovate.

Jay P. Madan, M.S.

Private Innovate entered into an executive employment agreement with Mr. Madan in October 2015, which was subsequently amended in February 2016, March 2017 and August 2017.

The agreement provided for an initial base salary of $90,000, which was increased to $150,000 effective July 1, 2016. The agreement provided that the 2016 base salary was to be deferred until the time of the Minimum Financial Milestone Event; however, if such Minimum Financial Milestone Event did not occur on or before March 15, 2017, Mr. Madan agreed to forfeit such base salary for the period of January 1, 2016, through December 31, 2016. The Minimum Financial Milestone Event occurred after March 15, 2017.

Commencing January 1, 2017, $90,000 of Mr. Madan's annual base salary was subjected to deferral, with such deferral and salary accrual continuing until the Minimum Financial Milestone Event occurred. So long as the Minimum Financial Milestone Event did not occur on or before March 15, 2018, Mr. Madan agreed to forfeit such 2017 deferred salary for the period of January 1, 2017 through December 31, 2017. As the First Milestone Event was achieved in April 2017, all deferred 2017 annual base salary was paid.

After the occurrence of the First Milestone Event, Mr. Madan's annual base salary increased to $180,000 and was not subject to deferral. Upon the occurrence of the Second and Third Financial Milestone Events, Mr. Madan's annual base salary increases to $210,000 and $250,000, respectively. Effective with the consummation of the Equity Issuance in January 2018, the Second and Third Milestone Events were achieved. Upon the occurrence of the Fourth Financial Milestone Event, Mr. Madan's annual base salary was to increase to $350,000.

The agreement also provides that Mr. Madan was eligible to receive a one-time lump sum cash bonus in the amount of $30,000 upon the occurrence of the Minimum Financial Milestone Event, a one-time lump sum cash bonus in the amount of $115,000 upon the occurrence of the Second Financial Milestone Event, a one-time lump sum cash bonus in the amount of $150,000 upon the occurrence of the Minimum Third Milestone Event, and a one-time lump sum cash bonus in the amount of $125,000 upon the occurrence of the Minimum Fourth Milestone Event. The Minimum Milestone Event was achieved in April 2017 and paid and the Second and Third Milestone Events were achieved effective with the consummation of the Equity Issuance in January 2018. The bonus amounts associated with the Second and Third Milestone Events were included in other accrued liabilities as of December 31, 2017.

For the months of July, August and September 2016, Mr. Madan was eligible for a discretionary monthly bonus in the amount of $1,500 per month. If a Minimum Financial Milestone Event had not occurred by March 15, 2017, Mr. Madan was eligible for a discretionary bonus of $90,000, awarded in Innovate's discretion upon the achievement of certain corporate objectives on or before December 31, 2017. This discretionary bonus was awarded and paid during 2017. Mr. Madan also received a discretionary bonus of $20,000 during 2017 as compensation for his board of director services.

During 2017, Mr. Madan was also eligible to receive periodic stock or option awards in the discretion of Private Innovate.

Amended and Restated Executive Employment Agreements with Drs. Laumas and Prior and Mr. Madan

On March 11, 2018, we entered into amended and restated executive employment agreements with each of Drs. Laumas and Prior and Mr. Madan (the "Executive Agreements"). Under the Executive Agreements, Drs. Laumas and Prior and Mr. Madan will be entitled to receive annual base salaries of $275,000, $300,000 and $285,000, respectively, subject to periodic adjustment as we may determine. Each of Drs. Laumas and Prior and Mr. Madan is generally eligible to participate in employee benefit and bonus programs established by the Company from time to time that may be applicable to our executives.

If we terminate any of the Executive Agreements other than "for cause," or if any of Drs. Laumas and Prior or Mr. Madan terminates his respective agreement for "Good Reason," the Executive Agreements provide that such executive will receive 12 months of his then-current base salary and up to 12 months of continuation of health insurance benefits, provided that such executive executes and does not revoke a release and settlement agreement in a form satisfactory to us.

Director Compensation – Private Innovate

Private Innovate did not have any directors in the years ended December 31, 2017 and 2016 who were not employed by Private Innovate.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The following table and the related notes present information on the beneficial ownership of shares of our capital stock as of March 9, 2018 (except where otherwise indicated) by:

- each of our directors;
- each of our named executive officers;
- all of our current directors and executive officers as a group; and
- each person, or group of affiliated persons, who are known by us to beneficially own more than 5% of the outstanding shares of our capital stock on an as converted basis.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Shares of common stock that may be acquired by an individual or group within 60 days of March 9, 2018, pursuant to the exercise of options or warrants, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table.

Except as indicated in the footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless otherwise indicated, the address for each stockholder listed is: c/o Innovate Biopharmaceuticals, Inc., 8480 Honeycutt Road, Suite 120, Raleigh, NC 27615.

Name and Address of Beneficial Owner	Shares Beneficially Owned	Percent of Outstanding
Principal Stockholders:		
BrynMawr Technology Holdings (1)	1,885,440	7.3%
Moonstar Family Group (2)	2,688,217	10.5%
The Sea Island Partnership (3)	2,892,298	11.3%
Triangle Healthcare Partners (4)	1,720,453	6.7%
UKR Partners LLC (5)	1,461,898	5.7%
Directors and Named Executive Officers:		
Christopher Prior, Ph.D. (6)	2,020,210	7.3%
Jay P. Madan (7)	1,009,152	4.3%
Sandeep Laumas, M.D. (8)	835,106	3.2%
June Almenoff, M.D.	-	*
Lorin K. Johnson, Ph.D. (9)	237,425	*
Anna Kazanchyan, M.D.	-	*
Anthony E. Maida III, Ph.D. (10)	48,992	*
Roy Proujanksy, M.D.	-	*
David H. Clarke (11)	171,845	*
Jonathan Clark	28,500	*
Stephen R. Brownsell	13,500	*
David Olert (12)	8,684	*
All directors and executive officers as a group (8 persons) (13)	4,240,885	14.8%

* Represents beneficial ownership of less than 1% of the shares of common stock

(1) The manager of BrynMawr Technology Holdings is Mark Costley.
(2) The managing member of Moonstar Family Group is Chris Durant.
(3) The manager of The Sea Island Partnership is Michael Huter.
(4) The managing member of Triangle Healthcare Partners is Cory Howes.
(5) Includes 1,461,898 shares and 117,661 warrants held by UKR Partners LLC. The manager of UKR Partners LLC is Thomas Gombar.
(6) Consists of 2,020,210 shares issuable upon the exercise of options held by Dr. Prior that are exercisable within 60 days of March 9, 2018.
(7) Includes 529,131 shares held by Mr. Madan, 129,593 shares held by Madan Global, Inc., 122,104 shares held by OM Healthcare Partners LLC, 122,104 shares held by OM Healthcare Partners II LLC, and 122,104 shares held by OM Healthcare Partners III LLC, and 74,116 shares issuable upon the exercise of options held by Mr. Madan that are exercisable within 60 days of March 9, 2018. Mr. Madan is affiliated with Madan Global, Inc. and with each of the named OM Healthcare Partner companies, and has voting and investment power over these shares, respectively.
(8) Includes 758,373 shares held by Bearing Circle Capital LLC and 76,733 shares issuable upon the exercise of options held by Dr. Laumas that are exercisable within 60 days of March 9, 2018. Dr. Laumas is affiliated with Bearing Circle Capital LLC and has voting and investment power over the shares held by Bearing Circle Capital LLC.
(9) Consists of 237,425 shares issuable upon the exercise of options held by Dr. Johnson that are exercisable within 60 days of March 9, 2018.
(10) Consists of 48,992 shares issuable upon the exercise of an option held by Dr. Maida that is exercisable within 60 days of March 9, 2018.
(11) Based on information provided on behalf of Mr. Clarke, includes 58,370 shares held by Mr. Clarke, 7,140 shares held by Leslie Clarke, Mr. Clarke's wife, and 106,335 shares held by GBS Holdings, Inc., an entity which may be deemed controlled by Mr. Clarke but which is owned by Leslie Clarke and the children of Mr. Clarke. Mr. Clarke may be deemed the indirect beneficial owner of these securities since he has shared sale, voting and investment control over the securities with his wife. The address of GSB Holdings, Inc. and Mr. Clarke is 14179 Laurel Trail, Wellington, Florida 33414.
(12) Includes 1,684 shares issuable upon the exercise of options held by Mr. Olert that are exercisable within 60 days of March 9, 2018.
(13) Includes 2,457,476 shares issuable upon the exercise of options held by the Company's current directors and executive officers that are exercisable within 60 days of March 9, 2018.

Equity Compensation Plan Information

The following table sets forth certain information as of December 31, 2017 about shares of common stock outstanding and available for issuance under Monster's 2012 Omnibus Incentive Plan.

	Number of Securities to be issued upon exercise of outstanding options and restricted stock	Weighted average exercise price of outstanding options	Number of Securities remaining available under equity compensation plans
Equity compensation plans approved by stockholders	1,683	$ 45.00	5
Equity compensation plans not approved by stockholders	—	—	—

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Related-Person Transaction Policy and Procedures

Our Board has adopted a written related person transaction policy setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy covers, with certain exceptions set forth in Item 404 of Regulation S-K, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, the amount involved exceeds $120,000 in any fiscal year and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our Audit Committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. Notwithstanding anything therein to the contrary, the policy is to be interpreted only in such a manner as to comply with Item 404 of Regulation S-K.

The Board of Directors of Monster had also adopted a policy that its executive officers, directors, nominees for election as a director, beneficial owners of more than five percent of any class of its common stock and any members of the immediate family of any of the foregoing persons were not permitted to enter into a related person transaction with the Company without the prior consent of its Audit Committee. Any request for Monster to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than five percent of any class of the Company's voting securities or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds $120,000 and such person would have has a direct or indirect interest, must have first been presented to the Company's Audit Committee for review, consideration and approval. In approving or rejecting any such proposal, the Audit Committee was to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person's interest in the transaction. We refer to this as the "Monster Related Person Transaction Policy."

Certain Related-Person Transactions

Described below are transactions occurring since January 1, 2016, and any currently proposed transactions to which we were a participant and in which:

- The amounts involved exceeded or will exceed one percent of the average of our total assets at year end for the last two completed fiscal years; and

- A director, executive officer, holder of more than five percent of our outstanding capital stock, or any member of such person's immediate family had or will have a direct or indirect material interest, other than compensation, termination and change of control arrangements that are described under the section titled "Executive Compensation" in this Annual Report on Form 10-K.

Unless otherwise noted below, each of these transactions was approved pursuant to the Monster Related Person Transaction Policy.

Loans:

On June 7, 2017, GSB Holdings, Inc., a family owned company of David Clarke, the then CEO and Chairman of the Board, loaned Monster $100,000 further to a promissory note and issued 10,204 three-year warrants at an exercise price of $20.00 in lieu of interest. On June 23, 2017, Monster issued 17,241 shares of common stock at $5.80 per share in exchange for the promissory note. The issuance price was $0.50 greater than the closing price of our common stock on the issuance date.

In 2016, as approved by the Private Innovate Board, Private Innovate made a non-interest bearing loan to Jay Madan, its President, and his affiliates for $135,000. Mr. Madan repaid $60,000 of the borrowed amount in 2016 and the remaining $75,000 of the borrowed amount was repaid in February 2018.

Restricted Shares:

In March 2017, Monster issued 7,000 shares of restricted common stock to David Clarke, the then Chairman of the Board, at a purchase price of $15.00 per share pursuant to a Private Placement Memorandum. Monster issued 10,000 shares of restricted common stock to the then Chairman of the Board in November 2017, and 2,500 shares of restricted stock in January 2018.

In November 2017, Monster issued 185,042 shares of restricted common stock to Strategic Planning Assets, LTD, a Hong Kong company, at a purchase price of $6.50 pursuant to a stock purchase agreement dated September 12, 2017. The purchase agreement called for the invested funds to be used to settle a debt owed by Monster below the amount recorded in its financial records. The number of shares to be issued was calculated using the full amount of the debt and at a share price equal to the average closing price of our common stock during the ten-day period prior to the stockholder approval of the transaction as voted on November 9, 2017.

Consulting Agreements:

In May 2016, Monster entered into a 10-week consulting agreement with Jonathan Orban, who was then serving as one of Monster's directors, which became effective on the effective date of its initial public offering. Further to the agreement, Monster agreed to pay Mr. Orban $250 per hour but no more than $10,000 per week. Monster also agreed to pay all of Mr. Orban's expenses incurred in connection with the performance of his consulting duties in an amount not to exceed $20,000. This Agreement was terminated in October 2016, and in connection therewith Monster paid Mr. Orban the aggregate sum of $80,000.

In June 2016, Monster entered into a one-year consulting agreement with Jawahar Tandon, the former Chief Executive Officer. Further to the agreement, Monster issued Mr. Tandon 125,000 restricted shares of common stock. Monster also agreed to pay all of Mr. Tandon's pre-approved reasonable expenses incurred in connection with the performance of his consulting duties.

The consulting arrangements described above were entered into prior to the adoption of the Monster Related Person Transaction Policy, but after presentation, consideration and approval by the Board of Monster.

Director and Officer Indemnification and Insurance:

Section 145 of the Delaware General Corporation Law authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act of 1933, as amended. Our amended and restated certificate of incorporation provides for indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law, and our amended and restated bylaws provide for indemnification of our directors, officers, employees and other agents to the maximum extent permitted by the Delaware General Corporation Law.

We have entered into indemnification agreements with our directors, whereby we have agreed to indemnify our directors to the fullest extent permitted by law, including indemnification against expenses and liabilities incurred in legal proceedings to which the director was, or is threatened to be made, a party by reason of the fact that such director is or was our director, provided that such director acted in good faith and in a manner that the director reasonably believed to be in, or not opposed to, the our best interest. At present, there is no pending litigation or proceeding involving any of our directors regarding which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

We maintain insurance policies that cover certain liabilities of our directors and officers arising out of claims based on actions or omissions that might be incurred by any director or officer in his capacity as such.

Item 14. Principal Accountant Fees and Services.

Independent Registered Public Accounting Firm

CohnReznick LLP audited Monster's consolidated financial statements for the years ended December 31, 2017 and 2016.

Audit Fees

Audit fees include fees for the audit of Monster's annual consolidated financial statements, fees for the review of Monster's interim consolidated financial statements, and fees for services that are normally provided by the independent registered public accounting firm in connection with statutory and regulatory filings or engagements. In 2016 this included reviews related to Monster's Public Offering. The aggregate fees billed by CohnReznick LLP for the profession services rendered to Monster for the audit of Monster's annual consolidated financial statements for the fiscal years 2017 and 2016, reviews of quarterly consolidated financial statements on Form 10-Q and Monster's Form S-1 filings were $191,000 and $389,000, respectively.

Audit-Related Fees

There was no assurance or related fees for services by CohnReznick LLP in the fiscal years of 2017 and 2016.

Tax Fees

There were no fees for services for tax compliance, tax advice or tax planning by CohnReznick LLP in the fiscal years 2017 and 2016.

All Other Fees

There were no other fees for services by CohnReznick LLP in the fiscal years 2017 and 2016.

Determination of Auditor Independence

There were no non-audit services provided by CohnReznick LLP that would need to be considered in determining auditor independence.

Audit Committee's Pre-Approval Policies

The Audit Committee pre-approves all services provided by our independent registered public accounting firm prior to the commencement of the engagement.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements

The financial statements required by this item are submitted in a separate section beginning on page F-1 of this annual report.

(a)(2) Financial Statement Schedules

Financial statement schedules have been omitted because they are either not required, not applicable, or the information is otherwise included.

(a)(3) Exhibits

EXHIBIT INDEX

EXHIBIT NO.		DESCRIPTION	FILED HEREWITH	INCORPORATED BY REFERENCE			
				FORM	FILE NO.	EXHIBIT	FILING DATE
2.1	+	Agreement and Plan of Merger and Reorganization by and among Monster Digital, Inc., Merger Sub and Innovate Biopharmaceuticals Inc., dated July 3, 2017		8-K	001-37797	2.1	July 6, 2017
2.2		Amendment, dated January 3, 2018, to Agreement and Plan of Merger and Reorganization by and among Monster Digital, Inc., Merger Sub and Innovate Biopharmaceuticals Inc., dated July 3, 2017		8-K	001-37797	2.1	January 5, 2018
2.3		Form of Support Agreement, by and between Monster Digital, Inc. and certain directors, officers and stockholders of Innovate Biopharmaceuticals Inc. (now IB Pharmaceuticals Inc.)		8-K	001-37797	2.2	July 6, 2017
2.4		Form of Support Agreement, by and between Innovate Biopharmaceuticals Inc. and the directors and executive officers and certain stockholders of Monster Digital, Inc. (now IB Pharmaceuticals)		8-K	001-37797	2.3	July 6, 2017
3.1		Certificate of Incorporation of the Company, as amended	X				
3.2		Amended and Restated Bylaws of the Company		8-K	001-37797	3.2	February 2, 2018
4.1		Form of Share Certificate	X				
4.2		Form of Warrant		8-K	001-37797	4.1	February 2, 2018
4.3		Senior Note dated January 29, 2018		8-K	001-37797	4.2	February 2, 2018
4.4		Subscription Agreement dated January 29, 2018		8-K	001-37797	10.1	February 2, 2018
4.5		Form of Warrant Certificate		S-1	333-207938	4.2	June 24, 2016
4.6		Form of Warrant Agreement by and between Monster Digital, Inc. and Corporate Stock Transfer, Inc.		S-1	333-207938	4.3	June 24, 2016
4.7		Warrant dated August 18, 2015 held by Noel Lee		S-1	333-207938	10.10	November 10, 2015
4.8		Registration Rights Agreement dated November 10, 2016 by and between Monster Digital, Inc. and Gibralt Capital Corporation		10-K	001-37797	10.23	March 31, 2017
10.1	†	Sublicense Agreement, dated February 19, 2016, between Innovate Biopharmaceuticals Inc. (now IB Pharmaceuticals Inc.) and Alba Therapeutics Corporation	X				
10.2	†	License Agreement, dated February 26, 2016, between Innovate Biopharmaceuticals Inc. (now IB Pharmaceuticals Inc.) and Alba Therapeutics Corporation	X				
10.3	†	Asset Purchase Agreement, dated December 23, 2014, between Innovate Biopharmaceuticals Inc. (now IB Pharmaceuticals Inc.) and Repligen Corporation	X				

10.4	†	Apaza License Agreement, dated April 19, 2013, between Innovate Biopharmaceuticals Inc. (now IB Pharmaceuticals Inc.) and Seachaid Pharmaceuticals, Inc., as amended	X

EXHIBIT NO.		DESCRIPTION	FILED HEREWITH	INCORPORATED BY REFERENCE			
				FORM	FILE NO.	EXHIBIT	FILING DATE
10.5		Note Purchase Agreement dated January 29, 2018		8-K	001-37797	10.1	February 2, 2018
10.6	#	Form of Director Indemnification Agreement		8-K	001-37797	10.2	February 2, 2018
10.7	#	Monster Digital, Inc. 2012 Omnibus Incentive Plan		S-1	333-207938	10.1	November 10, 2015
10.8	#	Form of Option Agreement and Option Grant Notice under the 2012 Omnibus Incentive Plan		S-1	333-207938	10.2	November 10, 2015
10.9	#	Form of Restricted Stock Award Agreement and Notice of Grant of Restricted Stock Award under the 2012 Omnibus Incentive Plan		S-1	333-207938	10.3	November 10, 2015
10.10	#	Form of Restricted Stock Unit Award Agreement and Notice of Grant of Restricted Stock Unit Award under 2012 Omnibus Incentive Plan		S-1	333-207938	10.4	November 10, 2015
10.11	#	Innovate Biopharmaceuticals Inc. 2015 Stock Incentive Plan, as amended	X				
10.12	#	Form of Incentive Stock Option Agreement under the 2015 Stock Incentive Plan	X				
10.13	#	Form of Nonstatutory Stock Option Agreement under the 2015 Stock Incentive Plan	X				
10.14	#	Form of Restricted Stock Purchase Agreement under the 2015 Stock Incentive Plan	X				
10.15	#	Consulting Agreement, dated May 7, 2015, by and between the Company and David Clarke		S-1	333-207938	10.11	November 10, 2015
10.16	#	Executive Employment Agreement, dated June 6, 2016, by and between the Company and David Olert		S-1	333-207938	10.21	November 10, 2015
10.17	#	Separation Agreement and Release of Claims, dated January 26, 2018, by and between the Company and David Olert	X				
10.18		Consulting Agreement, dated February 17, 2018, by and between the Company and David Olert	X				

EXHIBIT NO.		DESCRIPTION	FILED HEREWITH	INCORPORATED BY REFERENCE			
				FORM	FILE NO.	EXHIBIT	FILING DATE
10.19	#	Consulting Agreement, dated May 26, 2016, by and between the Company and Jonathan Orban		S-1	333-207938	10.22	November 10, 2015
10.20	#	Executive Employment Agreement, dated November 2, 2015, by and between Innovate Biopharmaceuticals Inc. (now IB Pharmaceuticals Inc.) and Christopher Prior, as amended	X				
10.21	#	Executive Employment Agreement, dated October 28, 2015, by and between Innovate Biopharmaceuticals Inc. (now IB Pharmaceuticals Inc.) and Sandeep Laumas, as amended	X				
10.22	#	Executive Employment Agreement, dated October 28, 2015, by and between Innovate Biopharmaceuticals Inc. (now IB Pharmaceuticals Inc.) and Jay Madan, as amended	X				
10.23	#	Executive Employment Agreement, dated March 9, 2018, by and between the Company and June Almenoff	X				
10.24	#	Non-Employee Director Compensation Policy	X				
10.25	#	Amended and Restated Executive Employment Agreement, dated March 11, 2018, by and between the Company and Sandeep Laumas	X				
10.26	#	Amended and Restated Executive Employment Agreement, dated March 11, 2018, by and between the Company and Christopher Prior	X				
10.27	#	Amended and Restated Executive Employment Agreement, dated March 11, 2018, by and between the Company and Jay Madan	X				
21.1		List of Subsidiaries	X				
23.1		Consent of CohnReznick LLP	X				
31.1		Certification of Principal Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				
31.2		Certification of Principal Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				

EXHIBIT NO.	DESCRIPTION	FILED HEREWITH	INCORPORATED BY REFERENCE			
			FORM	FILE NO.	EXHIBIT	FILING DATE
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
101.INS	XBRL Instance Document	X				
101.SCH	XBRL Taxonomy Extension Schema Document	X				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X				
101.DEF	XBRL Taxonomy Extension Definition Document	X				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document	X				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X				

+ Pursuant to Regulation S-K Item 601(b)(2), certain schedules (or similar attachments) to this exhibit have not been filed herewith. A list of omitted schedules (or similar attachments) is included in the agreement. The Company agrees to furnish supplementally a copy of any such schedule (or similar attachment) to the Securities and Exchange Commission upon request; provided, however, that the Company may request confidential treatment of omitted items.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment pursuant to Rule 24b-2 under the Securities Exchange Act of 1934.

# Indicates management contract or compensatory plan or arrangement.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 13, 2018

Innovate Biopharmaceuticals, Inc.

By /s/ Christopher Prior, Ph.D.
Name: Christopher Prior, Ph.D.
Title: Chief Executive Officer

Signature	Title	Date
/s/ Sandeep Laumas Sandeep Laumas, M.D.	Executive Chairman	March 13, 2018
/s/ Christopher Prior Christopher Prior, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	March 13, 2018
/s/ Jay P. Madan Jay P. Madan	President, Chief Business Officer, Interim Principal Financial Officer, Interim Principal Accounting Officer and Director (Principal Financial Officer and Principal Accounting Officer)	March 13, 2018
/s/ Lorin K. Johnson Lorin K. Johnson, Ph.D.	Director	March 13, 2018
/s/ Anna Kazanchyan Anna Kazanchyan, M.D.	Director	March 13, 2018
/s/ Anthony E. Maida III Anthony E. Maida III, Ph.D.	Director	March 13, 2018
/s/ Roy Proujansky Roy Proujansky, M.D.	Director	March 13, 2018

MONSTER DIGITAL, INC.
AND SUBSIDIARIES
CONSOLIDATED
FINANCIAL STATEMENTS

December 31, 2017 and 2016

CONTENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders

Innovate Biopharmaceuticals, Inc. (formerly known as Monster Digital, Inc.)

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Monster Digital, Inc. (the "Company") as of December 31, 2017 and 2016, and the related statements of operations, shareholders' equity (deficit) and cash flows for the years then ended, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Emphasis of Matter

On January 29, 2018, as described in Note 1 the Company spun-off principally all the assets of the Company and merged the remaining assets with IB Pharmaceuticals Inc. (formerly known as Innovate Biopharmaceuticals Inc.).

Substantial doubt about the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As further discussed in Note 2 to the accompanying consolidated financial statements, the Company has incurred net losses and negative cash flows from operating activities for the years ended December 31, 2017 and 2016 and has an accumulated deficit as of December 31, 2017. These conditions raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CohnReznick LLP

We have served as the Company's auditor since 2014.

Roseland, New Jersey
March 12, 2018

MONSTER DIGITAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
(Dollars in thousands, except par value)

	December 31,	
	2017	**2016**
ASSETS		
Current assets		
Cash	$ 426	$ 1,453
Accounts receivable, net of allowances of $271 and $253, respectively	90	856
Inventories	101	1,105
Prepaid expenses and other	46	619
Total current assets	663	4,033
Trademark	—	2,417
Deposits and other assets	14	14
Total assets	$ 677	$ 6,464
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 441	$ 268
Accrued expenses	692	1,786
Customer refund	125	1,840
Due to related parties	33	44
Notes payable, net	1,359	38
Total current liabilities	2,650	3,976
Commitments and contingencies		
Shareholders' equity (deficit)		
Preferred stock; 10,000,000 shares authorized — none issued	—	—
Common stock; $.0001 par value; 100,000,000 shares authorized; 1,436,360 and 778,501 shares issued and outstanding, respectively	1	1
Additional paid-in capital	38,039	34,575
Accumulated deficit	(40,013)	(32,088)
Total shareholders' equity (deficit)	(1,973)	2,488
Total liabilities and shareholders' equity (deficit)	$ 677	$ 6,464

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

MONSTER DIGITAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS
(Dollars in thousands, except per share amounts)

	Year Ended December 31,	
	2017	**2016**
Net sales	$ 1,883	$ 4,065
Cost of goods sold	1,947	3,329
Gross profit (loss)	(64)	736
Operating expenses		
Research and development	190	270
Selling and marketing	1,428	2,425
General and administrative	4,984	3,984
Trademark impairment	2,286	—
Total operating expenses	8,888	6,679
Operating loss	(8,952)	(5,943)
Other expenses (income)		
Interest and finance expense	93	825
Gain of settlement of customer refund	(920)	—
Gain on extinguishment of debt	(200)	—
Gain on debt conversion	—	(557)
Total other expenses (income)	(1,027)	268
Loss before income taxes	(7,925)	(6,211)
Provision for income taxes	—	2
Net loss	$ (7,925)	$ (6,213)
Warrant tender offer inducement charge	896	—
Net loss attributable to common shareholders	$ (8,821)	$ (6,213)
Loss per share		
Basic and diluted	$ (9.36)	$ (11.26)
Number of shares used in computation		
Basic and diluted	942	552

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

MONSTER DIGITAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
(Dollars in thousands)

	Common Stock		Preferred Stock		Additional Paid-in	Accumulated	Shareholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance December 31, 2015	370,287	$ —	—	$ —	$ 20,181	$ (25,875)	$ (5,694)
Issuance of preferred stock	—	—	280,243	—	2,393	—	2,393
Conversion of preferred to common stock	75,680	—	(280,243)	—	—	—	—
Exchange of debt for equity	78,224	—	—	—	3,520	—	3,520
Issuance of common stock and warrants in IPO, net of issuance costs	202,500	1	—	—	6,842	—	6,843
Issuance of restricted shares of common stock	3,325	—	—	—	—	—	—
Issuance of restricted shares of common stock, net of issuance costs	48,485	—	—	—	673	—	673
Amortization of non-cash stock-based compensation	—	—	—	—	966	—	966
Net loss	—	—	—	—	—	(6,213)	(6,213)
Balance December 31, 2016	778,501	1	—	—	34,575	(32,088)	2,488
Issuance of common stock, net of issuance costs	51,696	—	—	—	419	—	419
Issuance of common stock pursuant to stock option plan	103,061	—	—	—	—	—	—
Issuance of common stock pursuant to consulting arrangements	8,250	—	—	—	—	—	—
Warrants issued in connection with convertible notes	—	—	—	—	44	—	44
Issuance of common stock in connection with warrants exercise net of issuance costs	292,569	—	—	—	1,190	—	1,190
Conversion of related party debt into equity	17,241	—	—	—	100	—	100
Issuance of common stock pursuant to debt payment agreement	185,042	—	—	—	600	—	600
Amortization of non-cash stock-based compensation	—	—	—	—	1,111	—	1,111
Net loss	—	—	—	—	—	(7,925)	(7,925)
Balance December 31, 2017	1,436,360	$ 1	—	$ —	$ 38,039	$ (40,013)	$ (1,973)

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

MONSTER DIGITAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Dollars in thousands)

	Year ended December 31,	
	2017	**2016**
Cash flows from operating activities		
Net loss	$ (7,925)	$ (6,213)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of stock-based compensation	1,111	966
Amortization of deferred debt issuance costs and debt discount	10	740
Amortization of trademark	131	131
Trademark impairment	2,286	—
Gain on settlement of customer refund	(920)	—
Gain on extinguishment of debt	(200)	—
Gain on debt conversion	—	(557)
Provision for doubtful accounts	20	153
Changes in operating assets and liabilities:		
Accounts receivable	746	(365)
Inventories	1,004	(472)
Prepaid expenses and other	573	(478)
Accounts payable	173	(753)
Accrued expenses	(805)	(1,569)
Customer refund	(195)	(10)
Due to related party	(11)	—
Net cash used in operating activities	(4,002)	(8,427)
Cash flows from financing activities		
Proceeds from issuance of preferred stock, net	—	2,393
Proceeds from issuance of common stock, net	419	673
Issuance of common stock in connection with warrants exercise	1,190	—
Proceeds from the issuance of convertible notes	1,346	—
Debt discount	(80)	—
Proceeds from issuance of IPO common stock and warrants	—	8,151
Prepaid IPO Costs	—	(689)
Proceeds from short-term loan – related party	100	—
Proceeds from issuance of bridge financing	—	406
Payments on bridge financing	—	(462)
Proceeds from credit facility	168	641
Payments on credit facility	(168)	(845)
Payments on trademark note payable	—	(450)
Deferred financing costs	—	(57)
Net cash provided by financing activities	2,975	9,761
Net increase (decrease) in cash	(1,027)	1,334
Cash, beginning of the year	1,453	119
Cash, end of the year	$ 426	$ 1,453
Supplemental disclosure of cash flow information		
Cash paid during the year for:		
Interest	$ 6	$ 59
Income taxes	$ —	$ 2
Non-cash investing and financing activities:		
Conversion of related party debt into equity	$ 100	$ —
Warrants issued in connection with notes payable	$ 44	$ —
Exchange of debt for equity	$ 600	$ —
Reclassification of deferred IPO costs	$ —	$ 619
Exchange of debt for equity upon IPO	$ —	$ 3,520

The accompanying Notes to Consolidated Financial Statements are an integral part of these statements.

MONSTER DIGITAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization: Monster Digital, Inc. ("MDI"), a Delaware corporation (formed in November 2010), and its subsidiary, SDJ Technologies, Inc. ("SDJ") (collectively referred to as the "Company"), is an importer of high-end memory storage products, flash memory and action sports cameras marketed and sold under the Monster Digital brand name acquired under a long-term licensing agreement with Monster, Inc. The Company sources its products from China, Taiwan and Hong Kong. In preparation for the reverse merger (the "Merger"), as discussed below, in September 2017, MDI incorporated MD Holding Co. Inc. ("MDH"), a Delaware corporation, to be the parent company in the Spin Off that is also discussed below. In January 2018 the name of MD Holding Co. Inc. was changed to NLM Holding Co., Inc. ("NLM").

Public Offering: The Company closed its initial public offering (the "Offering") on July 13, 2016 and its common stock and warrants were listed on the Nasdaq Capital Market under the symbols "MSDI" and "MSDIW", respectively. The Offering generated gross proceeds of $9,132,750 on the sale of 202,500 common shares at $45.00 per share and 202,500 warrants at $0.10 per warrant.

The Merger: On July 3, 2017, the Company entered into an Agreement and Plan of Merger with Innovate Biopharmaceuticals Inc. ("Innovate"). Under the terms of the Merger Agreement, on January 29, 2018, the Company merged with Innovate with Innovate surviving the Merger and becoming a wholly-owned subsidiary of the Company. Subject to the terms of the Merger Agreement, Innovate stockholders received a number of newly issued shares of the Company's common stock determined using an exchange ratio as defined in the Merger Agreement. The exchange ratio was based on a pre-transaction valuation of $60 million for Innovate's business and $6 million for the Company's business. As a result, current stockholders of the Company collectively own approximately 9% and Innovate stockholders collectively own approximately 91% of the combined company on a pro-forma basis, subject to adjustment based on the Company's net cash balance and the relative capitalization of the two companies at closing, as described more fully in the Merger Agreement. Following the Merger, on January 29, 2018, stockholders of Innovate became the majority owners of the Company.

On September 27, 2017, Monster Digital, Inc. transferred all of its businesses and assets, including all shares of SDJ Technologies, Inc., and those liabilities of the Company not assumed by Innovate pursuant to the Merger to NLM. The shares of NLM were spun off pro rata to holders of the Company's common stock immediately prior to the Merger (the "Spin Off").

The Company filed a definitive proxy statement with the Securities and Exchange Commission on October 12, 2017 in order to obtain the required stockholder approval for the Merger and the Spin Off referenced above, as well as other related matters, and such approval was obtained and the Merger and Spin Off occurred on January 29, 2018.

Immediately prior to the effective time of the Merger, the Company effected a reverse stock split at a ratio of one new share for every ten shares of its common stock outstanding. Under the terms of the Merger Agreement, the Company issued shares of its common stock to Innovate's stockholders at an exchange ratio of 0.37813802 of a share of common stock (post reverse stock split) in exchange for each share of Innovate common stock outstanding at the time of the Merger. Innovate assumed $1.0 million of the Company's liabilities. Immediately following the Merger, MDI's corporate name was changed to "Innovate Biopharmaceuticals, Inc."

Reverse Stock Split: Immediately preceding the Merger, Monster Digital shares of common stock were subject to a one-for ten reverse stock split. All share and per share information in these consolidated financial statements, except for par value and authorized shares, have been amended to reflect the reverse stock split.

NOTE 1 — BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

Basis of Presentation: The Company's consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The accompanying consolidated financial statements do not give effect to the completion of the Merger or Spin Off.

Principles of Consolidation: The consolidated financial statements include accounts of MDI and SDJ. All significant intercompany transactions have been eliminated in consolidation.

Use of Estimates: The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities (including sales returns, price protection allowances, bad debts, inventory reserves, warranty reserves, and asset impairments), disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ significantly from those estimates.

Concentration of Cash: The Company maintains its cash in bank accounts which, at times, may exceed federally insured limits. The Company has not experienced any losses in such accounts. Management believes the Company is not exposed to any significant credit risk on its cash balances.

Accounts Receivable: Accounts receivable are carried at original invoice amount less allowance for doubtful accounts. Management determines the allowance for doubtful accounts by identifying troubled accounts and by using historical experience applied to an aging of accounts. Accounts receivable are written off when deemed uncollectible. Recoveries of receivables previously written off are recorded when received. Accounts receivable are considered to be past due if any portion of the receivable balance is outstanding for more than 90 days past the customer's granted terms. The Company does not charge interest on past due balances or require collateral on its accounts receivable. As of December 31, 2017, and 2016, the allowance for doubtful accounts is approximately $271,000 and $253,000, respectively.

Inventories: Inventories are stated at the lower of cost or net realizable value, with cost being determined on the weighted average cost method of accounting. The Company purchases finished goods and materials to assemble kits in quantities that it anticipates will be fully used in the near term. Changes in operating strategy, customer demand, and fluctuations in market values can limit the Company's ability to effectively utilize all products purchased and can result in finished goods with above-market carrying costs which may cause losses on sales to customers. The Company's policy is to closely monitor inventory levels, obsolescence and lower market values compared to costs and, when necessary, reduce the carrying amount of its inventory to its market value. As of December 31, 2017, and 2016, inventory on hand was comprised primarily of finished goods ready for sale.

NOTE 1 — BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

Fair Value of Financial Instruments: Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on the assumptions that market participants would use in pricing an asset or liability. Fair value is based on a hierarchy of valuation techniques, which is determined on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect the Company's own market assumptions. These two types of inputs create a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Quoted prices for identical instruments in active markets.
Level 2: Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.
Level 3: Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

The carrying amounts for other financial instruments, which include cash, accounts receivable, accounts payable, notes payable and line of credit, approximate fair value based upon their short-term nature and maturity.

Revenue Recognition: Revenue is realized or realizable and earned when all of the following criteria are met: (1) persuasive evidence of an arrangement exists, (2) the sales price is fixed or determinable, (3) collectability is reasonably assured, and (4) products have been shipped and the customer has taken ownership and assumed the risk of loss. Distributors and retailers take full ownership of their product upon delivery and sales are fully recognized at that time.

Revenue is reduced by reserves for price protection, sales returns, allowances and rebates. The Company's reserve estimates are based upon historical data as well as projections of sales, customer inventories, market conditions and current contractual sales terms. The Company's total sales related reserves were $40,000 at December 31, 2017. If the Company reduces the list price of its products, certain customers may receive a credit from the Company (i.e. price protection). The Company estimates the impact of such pricing changes on a regular basis and adjusts its allowances accordingly. Amounts charged to operations for price protection are calculated based on actual price changes on individual products and customer inventory levels. The reserve is then reduced by actual credits given to these customers at the time the credits are issued. The Company calculates the allowance for doubtful accounts and provision for sales returns and rebates based on management's estimate of the amount expected to be uncollectible or returned on specific accounts. The Company provides for future returns, price protection and rebates at the time the products are sold. The Company calculates an estimate of future returns of product by analyzing units shipped, units returned and point of sale data to ascertain consumer purchases and inventory remaining with retail to establish anticipated returns. Price protection is calculated on a product by product basis. The objective of price protection is to mitigate returns by providing retailers with credits to ensure maximum consumer sales. Price protection is granted to retailers after they have presented the Company an affidavit of existing inventory. The Company also offers market development credits to certain of its customers. These credits are also charged against revenue.

Shipping and Handling Costs: Historically, the Company has not charged its customers for shipping and handling costs, which are a component of marketing and selling expenses. These costs totaled approximately $87,000 in 2017 and $137,000 in 2016.

NOTE 1 — BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

Income Taxes: Deferred tax assets and liabilities are determined based on the temporary differences between the financial reporting and tax basis of assets and liabilities and net operating loss carryforwards, applying enacted statutory tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company uses a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more likely than not to be realized upon settlement. As of December 31, 2017, and 2016, there are no known uncertain tax positions.

The Company policy is to classify the liability for unrecognized tax benefits as current to the extent that it is more likely than not to be realized upon settlement and to the extent that the Company anticipates payment (or receipt) of cash within one year. The Company recognizes interest and penalties, if any, related to unrecognized tax benefits in the tax provision.

Product Warranty: The Company's memory products are sold under various limited warranty arrangements ranging from three years to five years on solid state drives, one year on camera products and a limited lifetime warranty on all other products. Company policy is to establish reserves for estimated product warranty costs in the period when the related revenue is recognized. The Company has the right to return defective products to the manufacturer. As of December 31, 2017, and 2016, the Company has established a warranty reserve of $40,000 and $118,000, respectively, which is included in accrued expenses in the accompanying consolidated balance sheets.

Research and Development: The Company incurs costs to improve the appeal and functionality of its products. Research and development costs are charged to expense when incurred.

Earnings (Loss) per Share: Basic earnings (loss) per share is calculated by dividing net earnings (loss) attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is calculated similarly but includes potential dilution from the exercise of common stock options, warrants and conversion of debt to equity, except when the effect would be anti-dilutive. Earnings (loss) per share is computed using the "treasury stock method" and the "if converted method". For 2017, outstanding warrants to acquire 154,416 shares of common stock (99,916 issued further to the Offering, 50,500 issued in connection with the conversion of preferred stock and bridge loans upon closing of the Offering and 4,000 other warrants), 1,683 stock options, and $1,384,500 in convertible notes payable have been excluded from the computation of diluted loss per share because their effect was anti-dilutive. For 2016, outstanding warrants to acquire 415,991 shares of common stock (202,500 issued further to the Offering, 140,501 issued in connection with the conversion of preferred stock and bridge loans upon closing of the Offering and 72,990 other warrants), 10,108 stock options, and $38,000 in convertible notes payable have been excluded from the computation of diluted loss per share because their effect was anti-dilutive.

Recently Issued Accounting Pronouncements — In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers (Topic 606).* ASU 2014-09 is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective in the first quarter of 2018 and requires either a retrospective or a modified retrospective approach to adoption. In anticipation of the Merger, the Company has not yet selected a transition method or evaluated the effect that that updated standard would have.

NOTE 1 — BUSINESS ACTIVITY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

In July 2015, the FASB issued ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*. This standard requires entities to measure most inventory "at the lower of cost and net realizable value," thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market (market in this context is defined as one of three different measures, one of which is net realizable value). The standard is effective for the Company prospectively beginning January 1, 2017. The adoption of this standard has not had a material impact to the Company.

In November 2015, the FASB issued ASU No. 2015-17, *Income Taxes (Topic 740), Balance Sheet Classification of Deferred Taxes*, which includes amendments that require deferred tax liabilities and assets be classified as non-current in a classified statement of financial position. The amendments in this ASU are effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Earlier application is permitted as of the beginning of an interim or annual reporting period. The amendments may be applied either prospectively to all deferred tax liabilities and assets or retrospectively to all periods presented. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which requires lessees to recognize assets and liabilities for the rights and obligations created by most leases on their balance sheet. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. ASU 2016-02 requires modified retrospective adoption for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. The Company is currently evaluating the impact the standard may have on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, *Improvements to Employee Share-Based Payment Accounting (Topic 718)*, which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. ASU 2016-09 was effective for the Company in the first quarter of 2017. The adoption of this standard did not have a material impact on the Company's consolidated financial statements and related disclosures.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations – Clarifying the Definition of a Business*, which clarifies the definition of a business to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The standard introduces a screen for determining when assets acquired are not a business and clarifies that a business must include, at a minimum, an input and a substantive process that contribute to an output to be considered a business. This standard is effective for fiscal years beginning after December 15, 2017, including interim periods within that reporting period. The Company does not expect this new guidance to have a material impact on its consolidated financial statements.

Other pronouncements issued by the FASB with future effective dates are either not applicable or not significant to the consolidated financial statements of the Company.

NOTE 2 — GOING CONCERN

As of December 31, 2017, the Company has incurred cumulative net losses from its inception of approximately $40 million and has incurred a loss in 2017 of approximately $8 million. These circumstances raise substantial doubt as to the Company's ability to continue as a going concern. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should the Company be unable to continue in existence.

NOTE 3 — DEBT FINANCING

Credit Facility

In June 2015, the Company secured an accounts receivable financing facility with Bay View Funding. The contract provides for maximum funding of $4 million and a factoring fee of 1.35% for the first 30 days and .45% for each 10-day period thereafter that the financed receivable remains outstanding. Upon the execution of this contract, the balance owed under a prior credit facility was repaid and the contract was terminated. There was no balance outstanding under this Facility as of December 31, 2017 and 2016 and the facility was not renewed at December 31, 2017.

Convertible Debt Financing

On July 24, 2017, the Company entered into a Private Placement Engagement Agreement with WestPark Capital, Inc. for the purpose of raising up to $1,150,000 in convertible debt. An aggregate of $540,000 in convertible debt raised in June and July 2017 prior to the consummation of the WestPark Capital, Inc. agreement are under the same terms. The Promissory Notes bear interest at 15% and are convertible to common stock concurrent with a potential merger (see Note 1) at the lesser of $7.50 per share or 75% of the average market value of the Company's common stock for the five days preceding the consummation of such merger. Otherwise, the Notes become due March 31, 2019. For every $2.50 in note principal purchased, investors receive one warrant, exercisable for five years, to purchase shares of common stock at $20.00. The Company raised $1,346,500 pursuant to this agreement and, as of December 31, 2017, a total of $1,346,500 in principal of the convertible Notes remains outstanding. Concurrent with the Merger the Notes converted to common stock at $4.40 per share. As of December 31, 2017, and 2016, a total of $38,000 in principal of convertible Notes payable that matured in the second quarter of 2015 remains outstanding.

Promissory Notes

From October 2015 through March 7, 2016, the Company issued promissory notes; the notes were due and payable at the earlier of one year from the date of issuance or the closing date of the Company's initial public offering, bear an interest rate of 15% that was accrued upon issuance, irrespective of whether the promissory note was outstanding for part or full term until maturity, and had a loan origination fee of $.225 for each dollar loaned. The loan origination fee associated with the notes as of December 31, 2015 was $756,000 and was recorded as accrued interest and debt discount to the notes payable and is being amortized over the life of the notes. Debt discount amortized as interest expense in the year ended December 31, 2016 was approximately $389,000. All principal, fees and interest were payable on the due date. In July 2016, the Company completed the Offering whereby 90% of the outstanding promissory notes totaling $3,024,000 were converted to 67,200 shares of common stock and 67,200 warrants at the offering price of $45.00 per share. The 15% accrued interest and the 22.5% origination fee were waived as part of the conversion. The remaining, unconverted $336,000 of promissory notes were paid out of the proceeds of the Offering along with the accrued interest and origination fee attributable to those notes.

NOTE 3 — DEBT FINANCING – (continued)

Notes payable consists of the following (in thousands):

	December 31, 2017	December 31, 2016
Note payable, convertible debt	$ 38	$ 38
Promissory notes payable, net of $35 debt discount and debt issuance cost of $75	1,321	—
Total	$ 1,359	$ 38

NOTE 4 — ACCRUED EXPENSES

Accrued expenses consist of the following (in thousands):

	December 31, 2017	December 31, 2016
Royalties	$ 180	$ 125
Reserve for charges against sales	40	334
Accrued purchase orders	—	158
Deferred gain	—	445
Others	472	724
Total	$ 692	$ 1,786

NOTE 5 — STOCKHOLDERS' EQUITY

Common Stock Purchase Warrants: In 2016, the Company issued warrants to acquire 375,510 shares of common stock, 202,500 issued further to the Offering and 140,501 issued in connection with the conversion of preferred stock and bridge loans upon closing of the Offering. In March and April 2016, the Company issued 17,100 warrants to purchase shares of common stock at $20.00 per share in connection with the issuance of restricted stock. In May 2017, 3,939 warrants to purchase common stock at $0.052 were exercised, in a cashless exercise, in exchange for the net equivalent shares of common stock. In June 2016, 10,204 warrants to purchase shares of common stock at $20.00 per share were issued in connection with the conversion of debt to equity. From July to August 2017, 53,860 warrants to purchase shares of common stock at $20.00 per share were issued in connection with the issuance of convertible promissory notes.

NOTE 5 — STOCKHOLDERS' EQUITY – (continued)

The Company filed Tender Offer Statements with the Securities and Exchange Commission on October 13, 2017, offering the Company's warrant holders the opportunity to purchase one share of common stock for each warrant held at a price of $4.50. The Company filed a definitive Proxy Statement with the Securities and Exchange Commission on October 12, 2017 to obtain shareholder approval for the Tender Offer and such approval was obtained. In November 2017 warrant holders exercised 288,750 warrants and the Company received net proceeds of approximately $1,190,000 after commission and fees. The Company considers the warrant amendment to be of an equity nature as the amendment allowed the warrant holder to exercise a warrant and receive a common share which represents an equity for equity exchange. Therefore, the change in the fair value before and after the modification of approximately $896,000 will be treated as a change in additional paid-in capital (APIC) as an inducement charge. The cash received upon exercise in excess of par is also accounted through APIC. As of December 31, 2017, and 2016 warrants to purchase 154,416 and 399,101 shares of common stock, respectively, were outstanding. Unexercised warrants expire from 2021 to 2022.

Restricted Shares: In August 2016, the Company authorized the issuance of 4,000 shares of restricted common stock pursuant to a services agreement with an investment relations firm and recognized $7,000 and $28,000 of compensation expense related to restricted shares in 2017. In addition, the Company authorized the issuance of 12,500 shares of restricted common stock to Jawahar Tandon pursuant to a consulting agreement and recognized the full $563,000 of compensation expense related to the restricted shares during the year ended December 31, 2016.

In November 2016, the Company entered into a securities purchase agreement providing for the issuance and sale to an investor of 33,333 shares of the Company's common stock. The shares issued in this private placement were sold at a purchase price per share of $15.00, for aggregate gross proceeds to the Company of approximately $500,000 and aggregate net proceeds to the Company, after deducting for placement agent fees and expenses, of approximately $446,000. The investor was issued an additional 8,000 shares in May 2017 in a non-cash transaction. The additional share issuance was intended to adjust the aggregate shares awarded to the investor in relation to future investment rounds that were transacted at $11.50 per share. Under the same private placement memorandum, the Company issued 15,151 shares of restricted common stock to its Chairman of the Board at a purchase price of $16.50 per share for gross proceeds of $250,000 and net proceeds of approximately $226,000.

In March 2017, the Company issued 22,600 shares of common stock at $15.00 per share in a private offering for aggregate gross proceeds of $339,000 and net proceeds, after deducting for commission and placement agent fees and expenses, of approximately $307,000. These shareholders were issued an additional 4,748 shares in July 2017 in a non-cash transaction to adjust the aggregate shares awarded to those investors in relation to a future investment round at $11.50. In April 2017, the Company issued an additional 11,600 shares at $11.50 for aggregate gross proceeds of $133,400 and net proceeds, after deducting for commission, of approximately $112,000.

On June 23, 2017, the Company issued 17,241 shares of common stock at $5.80 per share in exchange for a $100,000 promissory note dated June 7, 2017 due to GSB Holdings, Inc., a family owned company of David Clarke, who at the time was the Company's CEO and Chairman of the Board. The issuance price was $0.50 greater than the closing price of the Company's common stock on the issuance date.

During the second quarter of 2017, the Company issued 8,750 fully vested shares of restricted common stock and recognized $56,150 of non-cash, stock-based compensation at the time of issuance. The Company issued 1,500 of the 8,750 shares for product marketing, 1,250 shares pursuant to an employee severance agreement, 2,500 additional shares to its investor relations firm and 3,500 shares as compensation for the activities of a special committee of its Board.

Also, during the second quarter of 2017, the Company issued 9,500 shares of restricted common stock to certain employees. The Company recognized $22,000 of non-cash, stock-based compensation in 2017. Another $45,000 of stock-based compensation remains to be amortized over 16 months.

During the third quarter of 2017, the Company issued 3,000 shares of restricted common stock to the three independent members of its Board, recognizing $33,000 of non-cash, stock-based compensation in 2017 with no remaining amount to be amortized.

NOTE 5 — STOCKHOLDERS' EQUITY – (continued)

During the fourth quarter of 2017, the Company issued 7,000 shares of restricted common stock to three officers and one board member and issued 10,000 shares of restricted common stock to its Chairman and CEO, recognizing $76,188 of non-cash, stock-based compensation in 2017. Another $41,113 of stock-based compensation remains to be amortized over 22 months.

Preferred Stock: In March 2016, the Company issued a confidential Private Placement Memorandum ("PPM") for a maximum of 3,000,000 shares of Series A Convertible Preferred Stock, with a purchase price of $1.00 per share and convertible into one share of the Company's common stock and having an 8%, noncumulative dividend. Pursuant to the PPM, as of June 30, 2016, 2,802,430 shares of Series A Preferred Stock were subscribed for net proceeds of approximately $2.4 million. In July 2016, the Company completed the Offering in which all shares of Series A Preferred Stock was converted into 62,276 shares of common stock and 62,276 warrants at the public offering price of $45.00 per share and the issuance of 13,404 shares of common stock further to the conversion.

NOTE 6 — STOCK OPTIONS

In 2012, the Company's Board of Directors approved the 2012 Omnibus Incentive Plan (the "Plan") which allows for the granting of stock options, stock appreciation rights, awards of restricted stock and restricted stock units, stock bonuses and other cash and stock-based performance awards. A total of 97,035 shares of common stock have been approved and reserved for issuance under the Plan, which includes a 60,000 share increase approved by the Company's stockholders in May 2016. No options were granted in 2017, and during the same period, 4,610 options were forfeited for employees who were no longer with the Company and were returned to the pool of available options. There were 4,505 and 77,895 options available for grant at December 31, 2017 and 2016, respectively.

On the effective date of the Offering, 11,133 shares of restricted stock were granted to four executives of the Company. In January 2017, an additional 3,000 shares were granted to two of the same executives. Subsequent to the granting of the restricted stock, 10,133 shares were forfeited and returned to the option pool. Also concurrently with the Offering, 1,000 shares of restricted stock were granted to each of the Company's four outside directors. In January 2017, an additional 500 shares were granted to three of the directors. Since 4,500 of these shares were issued during the quarter fully vested, the Company recognized $29,000 of stock-based compensation at grant. Also in January 2017, 17,500 shares of restricted stock were issued to the Company's CEO fully vested and the Company recognized $266,000 of stock-based compensation at the time of the grant.

Also granted on the effective date of the Offering were previously approved options to acquire 8,650 common shares at an exercise price per share of $45.00 to four executives of the Company. Subsequent to the granting of the stock options, 6,967 options were forfeited and returned to the option pool.

In August 2016, pursuant to a services agreement and outside of the Plan, the Company granted options to acquire 3,814 shares of common stock to an investor relations firm.

The Company follows the provisions of ASC Topic 718, *Compensations – Stock Compensation* which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees and non-employee directors, including employee stock options. Stock compensation expense based on the grant date fair value estimated in accordance with the provisions of ASC 718 is generally recognized as an expense over the requisite service period.

NOTE 6 — STOCK OPTIONS – (continued)

In 2016, the following stock option grants were made:

Option Date	Options Granted	Exercise Price	Estimated Fair Value of Underlying Stock	Intrinsic Value
August 2016	600	$ 50.00	$ 30.00	None
August 2016	723	$ 70.00	$ 30.00	None
August 2016	999	$ 90.00	$ 30.00	None
August 2016	1,492	$ 110.00	$ 30.00	None

The Company utilizes the Black-Scholes valuation method to value stock options and recognizes compensation expense over the vesting period. The expected life represents the period that the Company's stock-based compensation awards are expected to be outstanding. The Company uses a simplified method provided in Securities and Exchange Commission Staff Accounting Bulletin No. 110 which averages an award's weighted average vesting period and contractual term for "plain vanilla" share options. The expected volatility was estimated by analyzing the historic volatility of similar public companies. No dividend payouts were assumed as the Company has not historically paid, and is not anticipating to pay, dividends in the foreseeable future. The risk-free rate of return reflects the weighted average interest rate offered for U.S. treasury rates over the expected life of the options.

A summary of significant assumptions used to estimate the fair value of the stock options granted in 2016 is as follows:

Weighted average fair value of options granted	$17.00
Expected term (years)	6.0 to 10.0
Risk-free interest rate	1.21% to 1.51%
Volatility	45.4%
Dividend yield	None

A summary of option activity for the Plan as of December 31, 2017 is represented as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contract Term (Years)	Aggregate Intrinsic Value
Options outstanding January 1, 2016	7,104	297.10	9.50	$ —
Granted	12,464	297.10	9.83	—
Forfeited	(13,275)	—	—	—
Options outstanding December 31, 2016	6,293	$ 45.00	9.50	—
Granted	—	—	—	—
Forfeited	(4,610)	—	—	—
Outstanding at December 31, 2017	1,683	$ 45.00	8.50	$ —

NOTE 6 — STOCK OPTIONS – (continued)

The following table summarizes restricted share activity for the year ended December 31, 2017:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding January 1, 2017	12,847	$ 38.70
Granted	119,410	11.50
Vested	(65,257)	12.00
Forfeited	(7,000)	30.60
Outstanding at December 31, 2017	60,000	$ 13.80

NOTE 6 — STOCK OPTIONS – (continued)

The Company recorded non-cash stock-based compensation related to stock options and restricted stock of $1,111,000 during the year ended December 31, 2017. The Company recorded non-cash stock-based compensation of $966,000 during the year ended December 31, 2016.

As of December 31, 2017, the total compensation expense related to unvested options and restricted stock not yet recognized totaled approximately $238,000. The weighted average vesting period over which the total compensation expense will be recorded related to unvested options and restricted stock not yet recognized at December 31, 2017 was approximately 7 months.

NOTE 7 — RELATED PARTY TRANSACTIONS

Borrowings: From time to time, the Company has received short-term, non-interest bearing loans from Tandon Enterprises, Inc. for the purpose of funding temporary working capital needs. For the year ended December 31, 2016, the Company borrowed $24,000, net of repayments. The $346,100 owed to Tandon Enterprises at June 30, 2016 was converted into 7,691 shares of common stock and warrants at the effective date of the Offering.

On June 7, 2017, GSB Holdings, Inc., a family owned company of David Clarke, the Company's then CEO and Chairman of the Board, loaned the Company $100,000 further to a promissory note and issued 10,204 three-year warrants at an exercise price of $20.00 in lieu of interest. On June 23, 2017, the Company issued 17,241 shares of common stock at $5.80 per share in exchange for the promissory note. The issuance price was $0.50 greater than the closing price of the Company's common stock on the issuance date.

Restricted Shares: In November 2016, the Company issued 15,152 shares of restricted common stock to its Chairman of the Board at a purchase price of $16.50 per share in a private placement transaction.

In March 2017, the Company issued 7,000 shares of restricted common stock to its Chairman of the Board at a purchase price of $15.00 per share in a private placement transaction. The Company issued 10,000 shares of restricted common stock to its Chairman of the Board in November 2017 and 2,500 shares of restricted stock in January 2018.

NOTE 8 — INCOME TAXES

The income tax provision for the years ended December 31, 2017 and 2016 was $0 and $2,000, respectively. The 2016 tax provision consists of state income taxes paid or currently payable. The deferred tax asset as of December 31, 2017 and 2016 is comprised of the following (dollars in thousands):

	2017	2016
Deferred tax assets		
Net operating losses	$ 9,525	$ 11,473
Accrued warranty	12	50
Other accrued expenses	948	484
Total deferred tax assets	10,485	12,007
Valuation allowance	(10,485)	(12,007)
Net deferred tax asset	$ —	$ —

NOTE 8 — INCOME TAXES – (continued)

The ultimate realization of the deferred tax asset is dependent upon the generation of future taxable income during the periods in which temporary differences become deductible. As of December 31, 2017, the state and federal net operating loss carryforwards are approximately $34,258,000 and $34,230,000, respectively. Due to the uncertainty surrounding the realization of these deferred tax assets, the Company has recorded a 100% valuation allowance. Net operating loss carryforwards expire between the years 2029 and 2036. Tax years ended December 31, 2017, 2016, 2015, 2014 and 2013 are open and subject to audit. The Company's net operating losses are subject to examination until those net operating losses are utilized and those tax years are closed.

The reconciliation of the U.S. statutory rate with the Company's effective test rate is summarized as follows:

	2017	2016
	% of pre-tax Earnings	% of pre-tax Earnings
Federal tax	(34.0)%	(34.0)%
State tax, net	(7.9)	(4.9)
Change in federal tax rate	56.1	—
Change in valuation allowance	(19.2)	33.3
Miscellaneous	5.0	5.6
	0.0%	0.0%

Management is not aware of any uncertain tax positions and does not expect the total amount of recognized tax benefits to change significantly in the next twelve months.

On December 22, 2017, the U.S. Government enacted comprehensive tax legislation commonly referred to as the Tax Cuts and Jobs Act (the "TCJA"). The TJCA makes broad changes to the U.S. tax code, including, but not limited to, (1) reducing the U.S federal corporate tax rate from 35% to 21%; (2) eliminating the corporate alternative minimum tax; (3) creating a new limitation on deductible interest expense; (4) creating the base erosion and anti-abuse tax, a new minimum tax; (5) limitation on the deductibility of certain executive compensation; (6) enhancing the option to claim accelerated depreciation deductions on qualified property, and (7) changing the rules related to uses and limitations of NOLs in tax years beginning after December 31, 2017.

The TCJA reduces the corporate tax rate to 21%, effective January 1, 2018. The accounting for this portion of the TCJA has caused a reduction to the net deferred tax assets before valuation allowance of $4.4 million for the year ended December 31, 2017. However, as discussed above, the Company maintains a full valuation allowance against its deferred tax assets. As a result, the $4.4 million reduction to the Company's deferred tax assets is offset by a corresponding $4.4 million reduction in the Company's valuation allowance, resulting in no net impact to the Company's tax provision.

NOTE 9 — CUSTOMER AND VENDOR CONCENTRATIONS

Customers:
Approximately 17%, 12%, 12% and 11% of the Company's gross sales were made to four customers for the year ended December 31, 2017. At December 31, 2017, the amount included in outstanding accounts receivable related to these four customers was approximately $189,000.

Approximately 34%, 8%, and 7% of the Company's gross sales were made to three customers for the year ended December 31, 2016. At December 31, 2016, the amount included in outstanding accounts receivable related to these three customers was approximately $433,000.

Vendors:
Approximately 47% of the Company's purchases were provided by one vendor for the year ended December 31, 2017. At December 31, 2017, there were no amounts payable related to this vendor.

Approximately 31% of the Company's purchases were provided by one vendor for the year ended December 31, 2016. At December 31, 2016, the amount in accounts payable related to this vendor was $6,000.

NOTE 10 — COMMITMENTS AND CONTINGENCIES

Royalty

The Company entered into the initial trademark license agreement with Monster, Inc. (formerly Monster Cable Products, Inc.) effective July 7, 2010. In 2012, the agreement was amended giving the Company exclusive rights to utilize the name “Monster Digital” on memory products for a period of 25 years (expires July 7, 2035) under the following payment schedule of royalties to Monster, Inc. This license agreement contains various termination clauses that include (i) change in control, (ii) breach of contract and (iii) insolvency, among others. The Company is required to remit royalty payments to Monster, Inc. on or before the 30th day following the end of each calendar quarter. At any time during the term of the agreement, a permanent license may be negotiated.

The royalty schedule became effective in August 2011 and was further amended in April 2012. As amended, royalties under this contract are as follows:

- Years 1 (2012) and 2: Royalties on all sales excluding sales to Monster, Inc. at a rate of four (4) percent, with no minimum.
- Years 3 through 6: Minimum royalty payments of $50,000 per quarter up to a maximum of four (4) percent of all sales excluding sales to Monster, Inc.
- Years 7 through 10: Minimum royalty payments of $125,000 per quarter up to a maximum of four (4) percent of all sales excluding sales to Monster, Inc.
- Years 11 through 15: Minimum royalty payments of $187,500 per quarter up to a maximum of four (4) percent of all sales excluding sales to Monster, Inc.
- Years 16 through 25: Minimum royalty payments of $250,000 per quarter up to a maximum of four (4) percent of all sales excluding sales to Monster, Inc.

Effective July 1, 2014, the royalty rate on certain products was reduced from 4% to 2% for a period of 12 months, based on a mutual understanding between the Company and the licensor.

NOTE 10 — COMMITMENTS AND CONTINGENCIES – (continued)

For the years ended December 31, 2017 and 2016, royalty expense amounted to approximately $180,000 and $371,000, respectively, which is included as a component of selling and marketing expenses in the accompanying consolidated statements of operations (see also Note 4). The Company reached a settlement related to royalty payments in December 2017 and owes a total of $180,000 at December 31, 2017 which was paid in January 2018. Pursuant to the settlement, the license agreement with Monster was terminated effective December 28, 2017. The Company recognized a gain of approximately $200,000 recorded as gain on extinguishment of debt. Further, the Company recorded a $2,286,000 impairment charge representing the net carrying amount of the trademark on the termination date.

Operating Leases

The Company occupied executive offices in Simi Valley, CA pursuant to a lease through January 31, 2018. Effective as of March 31, 2017, the Company terminated the lease by mutually accepted and favorable terms with the lessor. Effective April 1, 2017, the Company entered into a one-year lease for warehouse space in Ontario, CA. In January 2018 the Company was granted a lease termination with a return of deposit.

Customer payment agreements

In July 2015, the Company entered into an agreement with a customer under which the Company will pay the customer a total of $835,000 owed to the customer for promotional and other credits related to sales that occurred in 2014. The credits were accrued as contra-sales in 2014. Under the terms of the agreement, there is no interest and the Company was required to make 12 monthly payments of $65,000 beginning in August 2015, and one final payment of $65,000 in August 2016. There is a balance owed of $57,000 at December 31, 2017, such balance attributed to the Spin Off.

In January 2017, the Company entered into an agreement with a customer under which the Company settled an amount due of $1.84 million for $1.5 million, recording a $341,000 deferred gain and recognizing a current period gain of $68,000. The settlement included an initial payment of $250,000 with the remaining balance to be paid in monthly installments through December 2018. The Company and the customer entered into an addendum to the agreement in September 2017 whereby the customer agreed to accept a one-time payment of $600,000. The funds for this payment are from an investor who was offered shares of common stock below market and, as such, were held in escrow pending stockholder approval as one of the proposals in the Company's proxy statement. The Company obtained the necessary stockholder approval and the obligation is paid in full as of December 31, 2017. The Company recognized a total gain during the year ended December 31, 2017 of approximately $920,000 on settlement of the customer refund.

Legal matters

The Company is subject to certain legal proceedings and claims arising in connection with the normal course of its business.

On February 16, 2016, the Company received a letter from GoPro, Inc., or GoPro, alleging that the Company infringes on at least five U.S. patents held by GoPro, and requesting that confirm in writing that the Company will permanently cease the sale and distribution of its Villain camera, along with any camera accessories, including the waterproof camera case and standard housing. The five patents specifically identified by GoPro in the letter were U.S. Patent No. D710,921: camera housing design, U.S. Patent No. D702,747: camera housing design, U.S. Patent No. D740,875: camera housing design, U.S. Patent No. D737,879: camera design and U.S. Patent No. 721,935: camera design. Based upon the Company's preliminary review of these patents, the Company believes it has some defenses to GoPro's allegations, although there can be no assurance that the Company would be successful in defending against these allegations or reaching a business resolution that is satisfactory to the Company. In addition, the Company began marketing and selling the camera under the name "Monster Vision" and phasing out the Villain" name. The Company had no correspondence from GoPro after the Company instituted the name change. The Company has subsequently discontinued new sales of action sports cameras.

NOTE 10 — COMMITMENTS AND CONTINGENCIES – (continued)

The supplier of the Company's Villain camera has contractually represented and warranted that it owns or has paid royalties to any and all intellectual property, designs, software, hardware, packaging, components, manuals and any other portion, part or element that is or may be subject to the Villain and the parts and accessories thereof sourced by the supplier. This supplier has contractually agreed to pay any claims, damages, or costs that the Company suffers as a result of the patent infringement or a violation of international, U.S. or state laws or regulations as detailed in the prior sentence.

On September 15, 2017, a putative class action complaint (the " Class Complaint") was filed in the United States District Court for the Central District of California against the Company, David H. Clarke, the Company's then Chief Executive Officer and then a member of the Company's Board of Directors ("Clarke"), Jonathan Clark ("Clark"), the Company's then Interim President and then a member of the Company's Board of Directors, Robert Machinist ("Machinist"), then a member of the Registrant's Board of Directors, Christopher Miner ("Miner"), then a member of the Company's Board of Directors and Steven Barre ("Barre"), then a member of the Company's Board of Directors (Messrs. Clarke, Clark, Machinist, Miner and Barre are hereinafter referred to as the "Individual Defendants").

The Class Complaint sought class status on behalf of all of the Company's public stockholders and alleged violations by the Company and the Individual Defendants of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and the rules promulgated thereunder, and secondary control person liability against the Individual Defendants under Section 20(a) of the Exchange Act primarily related to the Merger. The Class Complaint sought to enjoin the Company and the Individual Defendants from proceeding with an anticipated stockholder vote on the Merger or consummating the Merger, unless and until the Company disclosed certain alleged material information which the Class Complaint alleges has been omitted from the Company's proxy statement or in the event the Merger was consummated, to recover an unspecified amount of damages resulting from the Individual Defendants' alleged violations Sections 14(a) and 20(a) of the Exchange Act.

The Class Complaint was withdrawn in November 2017.

State of Delaware
Secretary of State
Division of Corporations
Delivered 07:15 PM 11/09/2010
FILED 07:05 PM 11/09/2010
SRV 101073213 - 4896296 FILE

CERTIFICATE OF INCORPORATION

OF

WRASP 35, Inc.

(Pursuant to Section 102 of the Delaware General Corporation Law)

1. The name of the corporation is WRASP 35, Inc. (the "Corporation"),

2. The address of its registered office in the State of Delaware is 1811 Silverside Road, Wilmington, Delaware 19810, County of New Castle. The name of its registered agent at such address is Vcorp Services, LLC.

3. The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware (the "DGCL").

4. The Corporation is to have perpetual existence.

5. The total number of shares of capital stock which the Corporation shall have authority to issue is: one hundred ten million (110,000,000). These shares shall be divided into two classes with one hundred million (100,000,000) shares designated as common stock at $.0001 par value (the "Common Stock") and ten million (10,000,000) shares designated as preferred stock at $.0001 par value (the "Preferred Stock").

The Preferred Stock of the Corporation shall be issued by the Board of Directors of the Corporation in one or more classes or one or more series within any class and such classes or series shall have such voting powers, full or limited, or no voting powers, and such designations, preferences, limitations or restrictions as the Board of Directors of the Corporation may determine, from time to time.

Holders of shares of Common Stock shall be entitled to cast one vote for each share held at all stockholders' meetings for all purposes, including the election of directors. The Common Stock does not have cumulative voting rights.

No holder of shares of stock of any class shall be entitled as a matter of right to subscribe for or purchase or receive any part of any new or additional issue of shares of stock of any class, or of securities convertible into shares of stock of any class, whether now hereafter authorized or whether issued for money, for consideration other than money, or by way of dividend.

6. The Board of Directors shall have the power to adopt, amend or repeal the by-laws of the Corporation.

7. No director shall be personally liable to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty by such director as a director. Notwithstanding the foregoing sentence, a director shall be liable to the extent provided by applicable law, (i) for breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the DGCL or (iv) for any transaction from which the director derived an improper personal benefit. If the DGCL hereafter is amended to authorize the further elimination or limitation of the liability of directors, then the liability of a director of the Corporation, in addition to the limitation on personal liability provided herein, shall be limited to the fullest extent permitted by the amended DGCL. No amendment to or repeal of this Article 7 shall apply to or have any effect on the liability or alleged liability of any director of the Corporation for or with respect to any acts or omissions of such director occurring prior to such amendment,

8. The Corporation shall indemnify, to the fullest extent permitted by Section 145 of the DGCL, as amended from time to time, each person that such section grants the Corporation the power to indemnify.

9. The name and mailing address of the incorporator is Melanie Figueroa, c/o Richardson & Patel LLP, 420 Lexington Avenue, Suite 2620, New York, NY 10170.

IN WITNESS WHEREOF, the undersigned, being the incorporator hereinbefore named, has executed, signed and acknowledged this certificate of incorporation this 9th day of November, 2010.

/s/ Melanie Figueroa
Melanie Figueroa
Incorporator

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:01 PM 09/30/2011
FILED 03:22 PM 09/30/2011
SRV 111060047 - 4896296 FILE

STATE OF DELAWARE
CERTIFICATE OF AMENDMENT
OF CERTIFICATE OF INCORPORATION
OF WRASP 35, INC.

The corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware does hereby certify:

1. The name of the Corporation (hereinafter called the "Corporation") is WRASP 35, Inc.

2. The Certificate of Incorporation of the Corporation is hereby amended by striking out Article 1 thereof and by substituting in lieu of said Article the following new Article 1

"The name of the corporation is AOTS 35, Inc. (the "Corporation")."

3. The amendment of the Certificate of Incorporation of the Corporation herein certified was duly adopted, pursuant to the provisions of Section 242 of the General Corporation Law of the State of Delaware, by at least a majority of the outstanding shares of common stock entitled to vote.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be executed this 27th day of September, 2011.

By: /s/ Anthony C. Pintsopoulos
Anthony C. Pintsopoulos
Secretary and Director

State of Delaware
Secretary of State
Division of Corporations
Delivered 04:59 PM 10/20/2011
FILED 03:39 PM 10/20/2011
SRV 111121222 - 4896296 FILE

CERTIFICATE OF CHANGE OF LOCATION OF REGISTERED OFFICE AND OF REGISTERED AGENT

AOTS 35, INC.

It is hereby certified that:

1. The name of the corporation (hereinafter called the "corporation") is:

AOTS 35, INC.

2. The registered office of the corporation within the State of Delaware is hereby changed to 2711 Centerville Road, Suite 400, City of Wilmington 19808, County of New Castle.

3. The registered agent of the corporation within the State of Delaware is hereby changed to Corporation Service Company, the business office of which is identical with the registered office of the corporation as hereby changed.

4. The corporation has authorized the changes hereinbefore set forth by resolution of its Board of Directors.

Signed on October 13, 2011

By: /s/ Anthony C. Pintsopoulos
Anthony Pintsopoulos
Chief Financial Officer

State of Delaware
Secretary of State
Division of Corporations
Delivered 01:28 PM 06/01/2012
FILED 01:28 PM 06/01/2012
SRV 120691709 - 4896296 FILE

STATE OF DELAWARE

SECOND AMENDMENT TO
CERTIFICATE OF INCORPORATION
OF
AOTS 35, INC.

The corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware does hereby certify:

1. The name of the corporation is AOTS 35, Inc. (the "Corporation").

2. The Certificate of Amendment of Certificate of Incorporation of the Corporation is hereby amended by striking out Article 1 thereof and by substituting in lieu of said Article the following new Article 1

"The name of the corporation is Tandon Digital, Inc. (the "Corporation")."

3. The Second Amendment to Certificate of Incorporation of the Corporation herein certified was duly adopted, pursuant to the provisions of Section 242 of the General Corporation Law of the State of Delaware, by at least a majority of the outstanding shares of common stock entitled to vote.

IN WITNESS WHEREOF, the Corporation has caused this Second Amendment to Certificate of Incorporation to be executed this 29th day of May, 2012.

By: /s/ Anthony Pintsopoulos
Anthony Pintsopoulos
Secretary and Director

State of Delaware
Secretary of State
Division of Corporations
Delivered 02:24 PM 06/04/2012
FILED 02:22 PM 06/04/2012
SRV 120699692 - 4896296 FILE

CERTIFICATE OF AMENDMENT
TO
CERTIFICATE OF INCORPORATION
OF
TANDON DIGITAL, INC.

a Delaware corporation

Tandon Digital, Inc., a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "Corporation"),

DOES HEREBY CERTIFY:

FIRST: That Article 5 of the Certificate of Incorporation of the Corporation, as amended, is amended to insert the following paragraph immediately following the last sentence of paragraph 4:

"Upon the filing and effectiveness (the "Effective Time") of this Certificate of Amendment with the Delaware Secretary of State, every one (1) outstanding share of Common Stock shall without further action by this Corporation or the holder thereof be split into and automatically become four (4) shares of Common Stock (the "Stock Split"). The number of authorized shares of Common Stock of the Corporation and the par value of the Common Stock shall remain as set forth in this Certificate of Incorporation, as amended."

SECOND: The amendment set forth has been duly approved by the Board of Directors of the Corporation and by the Stockholders entitled to vote thereon.

THIRD: That said amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, I, the undersigned, being the President and Secretary of the Corporation, for the purpose of amending the Certificate of Incorporation of the Corporation pursuant to Section 242 of the Delaware General Corporation Law, do make and file this Certificate of Amendment,hereby declaring and certifying that the facts herein stated are true and accordingly have hereunto set my hand, as of this 4th day of June, 2012.

By: /s/ Jawahar Tandon
Jawahar Tandon
President and Secretary

State of Delaware
Secretary of State
Division of Corporations
Delivered 01:44 PM 03/18/2014
FILED 01:44 PM 03/18/2014
SRV 140344791 - 4896296 FILE

STATE OF DELAWARE
CERTIFICATE FOR RENEWAL
AND REVIVAL OF CHARTER

The corporation organized under the laws of the State of Delaware, the charter of which was voided for non-payment of taxes and/or for failure to file a complete annual report, now desires to procure a restoration, renewal and revival of its charter pursuant to Section 312 of the General Corporation Law of the State of Delaware, and hereby certifies as follows:

1. The name of the corporation is Tandon Digital, Inc.

2. The Registered Office of the corporation in the State of Delaware is located at 2711 Centerville Rd Suite 400 (Street),

in the City of Wilmington, County of New Castle Zip Code 19808. The name of the Registered Agent at such address upon whom process against this Corporation may be served is Corporation Service Company.

3. The date of filing of the Corporation's original Certificate of Incorporation in Delaware was November 9, 2010

4. The renewal and revival of the charter of this corporation is to be perpetual.

5. The corporation was duly organized and carried on the business authorized by its charter until the 1st day of March A.D. 2014, at which time its charter became inoperative and void for non-payment of taxes and/or failure to file a complete annual report and the certificate for renewal and revival is filed by authority of the duly elected directors of the corporation in accordance with the laws of the State of Delaware.

By: /s/ Jawahar Tandon
Authorized Officer

Name: Jawahar L. Tandon CEO
Print or Type

CERTIFICATE OF AMENDMENT
OF THE
CERTIFICATE OF INCORPORATION
OF TANDON DIGITAL, INC.

Vivek Tandon and Jawahar Tandon do hereby certify that:

1. They are the duly elected and acting President and Secretary, respectively, of TANDON DIGITAL, INC., a Delaware corporation (the "Corporation").

2. Article I of the Certificate of Incorporation of the Corporation is amended and restated in its entirety to read as follows:

"I

The name of this Corporation is Monster Digital, Inc."

3. The Corporation's Board of Directors has duly approved the foregoing Certificate of Amendment of the Certificate of Incorporation of the Corporation.

4. The foregoing Certificate of Amendment of the Certificate of Incorporation of the Corporation has been duly approved by the required vote of the stock of the Corporation in accordance with Sections 242 of the General Corporation Law of Delaware.

5. All other provisions of the Certificate of Incorporation of the Corporation remain in full force and effect.

6. This Certificate of Amendment of the Certificate of Incorporation of the Corporation shall become effective upon its filing in accordance with Section 103(d) of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, the undersigned have executed this Certificate of Amendment of the Certificate of Incorporation of the Corporation on August 25, 2015.

/s/ Vivek Tandon
Vivek Tandon, President

/s/ Jawahar Tandon
Jawahar Tandon, Secretary

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "MONSTER DIGITAL, INC.", FILED IN THIS OFFICE ON THE SEVENTH DAY OF JANUARY, A.D. 2016, AT 1:54 O'CLOCK P.M.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.

/s/ Jeffrey W. Bullock
Jeffrey W. Bullock, Secretary of State

4896296 8100
SR# 20160098142

Authentication: 201634325
Date: 01-07-16

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 01:54 PM 01/07/2016
FILED 01:54 PM 01/07/2016
SR 20160098142 - File Number 4896296

STATE OF DELAWARE
CERTIFICATE OF AMENDMENT
OF
CERTIFICATE OF INCORPORATION
OF

MONSTER DIGITAL, INC.

Monster Digital, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Company"), hereby certifies as follows:

1. That the fifth paragraph of article 5 of the Certificate of Incorporation, as amended, of the Company is hereby restated in full as follows:

"Upon filing and effectiveness of this Certificate of (the "Effective Time"), each 11.138103 shares of common stock issued and outstanding immediately prior thereto, shall be automatically combined into one (1) share of common stock (the "Reverse Stock Split"). No fractional shares shall be issued to the stockholders by reason of the Reverse Stock Split. In lieu thereof, each fractional share shall be rounded up or down to the next whole share. Each certificate that immediately prior to the Effective Time represented shares of common stock ("Old Certificates") shall thereafter represent that number of shares of common stock into which the shares of common stock represented by the Old Certificate shall have been combined, subject to the treatment of fractional shares as described above. The number of authorized shares of common stock of the corporation and the par value of the common stock shall remain as set forth in the corporation's certificate of incorporation, as amended."

2. That the foregoing amendment has been duly adopted in accordance with the provisions of Section 242 of the Delaware General Corporation Law **("DGCL"),** by approval of the board of directors of the Company and, in accordance with the provisions of Section 228 of the DGCL, by the holders of outstanding common stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted. There are no shares of the Company's preferred stock outstanding.

3. The Effective Time of the amendment herein certified shall be upon filing this certificate of amendment,

[*signature page follows*]

IN WITNESS WHEREOF, the Company has caused this Certificate of Amendment of Certificate of Incorporation to be duly executed by its authorized officer this 6th day of January, 2016.

By: /s/ David H. Clarke
David H. Clarke
Chief Executive Officer

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "MONSTER DIGITAL, INC.", FILED IN THIS OFFICE ON THE SIXTH DAY OF JUNE, A.D. 2016, AT 5:10 O'CLOCK P.M.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.

/s/ Jeffrey W. Bullock

Jeffrey W. Bullock, Secretary of State

4896296 8100

SR# 20164319980

Authentication : 202440012

Date : 06-06-16

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 05:10 PM 06/06/2016
Filed 05:10 PM 06/06/2016
SR 20164319980 - File Number 4896296

STATE OF DELAWARE
CERTIFICATE OF AMENDMENT
OF
CERTIFICATE OF INCORPORATION
OF

MONSTER DIGITAL, INC.

Monster Digital, Inc., a corporation organized and existing under the laws of the State of Delaware (the "Company"), hereby certifies as follows:

1. That the fifth paragraph of article 5 of the Certificate of Incorporation, as amended, of the Company is hereby restated in full as follows:

"Upon filing and effectiveness of this Certificate of (the "Effective Time"), each 1.2578616 shares of common stock issued and outstanding immediately prior thereto, shall be automatically combined into one (1) share of common stock (the "Reverse Stock Split"). No fractional shares shall be issued to the stockholders by reason of the Reverse Stock Split. In lieu thereof, each fractional share shall be rounded up or down to the next whole share. Each certificate that immediately prior to the Effective Time represented shares of common stock (''Old Certificates") shall thereafter represent that number of shares of common stock into which the shares of common stock represented by the Old Certificate shall have been combined, subject to the treatment of fractional shares as described above. The number of authorized shares of common stock of the corporation and the par value of the common stock shall remain as set forth in the corporation's certificate of incorporation, as amended."

2. That the foregoing amendment has been duly adopted in accordance with the provisions of Section 242 of the Delaware General Corporation Law **("DGCL"),** by approval of the board of directors of the Company and, in accordance with the provisions of Section 228 of the DGCL, by the holders of outstanding common stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted. There are no shares of the Company's preferred stock outstanding.

3. The Effective Time of the amendment herein certified shall be upon filing this certificate of amendment.

[*signature page follows*]

IN WITNESS WHEREOF, the Company has caused this Certificate of Amendment of Certificate of Incorporation to be duly executed by its authorized officer this 6th day of June, 2016.

By: /s/ David H. Clarke
David H. Clarke
Chief Executive Officer

STATE OF DELAWARE
CERTIFICATE OF AMENDMENT
OF
CERTIFICATE OF INCORPORATION
OF

MONSTER DIGITAL, INC.

Monster Digital, Inc., a corporation organized and existing under the laws of the State of Delaware (the “Company”), hereby certifies as follows:

1. That the fifth paragraph of article 5 of the Certificate of Incorporation, as amended, of the Company is hereby restated in full as follows:

"Upon filing and effectiveness of this Certificate of (the "Effective Time"), each 1.06 shares of common stock issued and outstanding immediately prior thereto, shall be automatically combined into one (1) share of common stock (the "Reverse Stock Split"). No fractional shares shall be issued to the stockholders by reason of the Reverse Stock Split. In lieu thereof, each fractional share shall be rounded up or down to the next whole share. Each certificate that immediately prior to the Effective Time represented shares of common stock ("Old Certificates") shall thereafter represent that number of shares of common stock into which the shares of common stock represented by the Old Certificate shall have been combined, subject to the treatment of fractional shares as described above. The number of authorized shares of common stock of the corporation and the par value of the common stock shall remain as set forth in the corporation's certificate of incorporation, as amended."

2. That the foregoing amendment has been duly adopted in accordance with the provisions of Section 242 of the Delaware General Corporation Law ("**DGCL**"), by approval of the board of directors of the Company and, in accordance with the provisions of Section 228 of the DGCL, by the holders of outstanding common stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted. There are no shares of the Company's preferred stock outstanding.

3. The Effective Time of the amendment herein certified shall be upon filing this certificate of amendment.

[*signature page follows*]

IN WITNESS WHEREOF, the Company has caused this Certificate of Amendment of Certificate of Incorporation to be duly executed by its authorized officer this 23rd day of June, 2016.

By: /s/ David H. Clarke
David H. Clarke
Chief Executive Officer

CERTIFICATE OF CORRECTION
FILED TO CORRECT A CERTAIN ERROR IN THE
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION OF
INNOVATE BIOPHARMACEUTICALS, INC.
FILED IN THE OFFICE OF THE SECRETARY OF STATE
OF THE STATE OF DELAWARE
ON JANUARY 29, 2018

Innovate Biopharmaceuticals, Inc., a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "**Company**"),

DOES HEREBY CERTIFY THAT:

1. The name of the Company is Innovate Biopharmaceuticals, Inc.

2. An Amended and Restated Certificate of Incorporation for the Company was filed with the Secretary of State of the State of Delaware on January 29, 2018 (the "**Restated Charter**"), and said Restated Charter requires correction as permitted by subsection (f) of Section 103 of the General Corporation Law of the State of Delaware.

3. The Restated Charter, in its entirety, is an inaccurate record of the corporate action therein referred to, in that it was filed in error, as it did not receive proper formal approval prior to the time of such execution and filing.

4. The inaccuracy or defect of said Restated Charter is to be corrected is as follows: The Restated Charter was filed in error. The Company intended to file a Certificate of Amendment, attached hereto as Exhibit A.

5. The Restated Charter is hereby replaced in its entirety as set forth on Exhibit A attached hereto.

IN WITNESS WHEREOF, the Company has caused this certificate of correction to be signed by a duly authorized officer of the Company on this 12th day of March, 2018.

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Jay P. Madan
Name: Jay P. Madan
Title: President

EXHIBIT A

STATE OF DELAWARE
CERTIFICATE OF AMENDMENT
OF THE
CERTIFICATE OF INCORPORATION
OF
MONSTER DIGITAL, INC.

Monster Digital, Inc., a Delaware corporation (the "**Corporation**"), hereby certifies as follows:

1. Article I of the Certificate of Incorporation of the Corporation, as amended (the "**Certificate**") is hereby amended and restated to read in its entirety as follows:

"1. The name of the corporation is Innovate Biopharmaceuticals, Inc. (the "Corporation"),"

2. Article V of the Certificate is hereby amended and restated to read in its entirety as follows:

"5. The total number of shares of capital stock which the Corporation shall have authority to issue is: three hundred and sixty million (360,000,000). These shares shall be divided into two classes with three hundred and fifty million (350,000,000) shares designated as common stock at $.0001 par value (the "Common Stock") and ten million (10,000,000) shares designated as preferred stock at $.0001 par value (the "Preferred Stock").

The Preferred Stock of the Corporation shall be issued by the Board of Directors of the Corporation in one or more classes or one or more series within any class and such classes or series shall have such voting powers, full or limited, or no voting powers, and such designations, preferences, limitations or restrictions as the Board of Directors of the Corporation may determine, from time to time.

Holders of shares of Common Stock shall be entitled to cast one vote for each share held at all stockholders' meetings for all purposes, including the election of directors. The Common Stock does not have cumulative voting rights.

No holder of shares of stock of any class shall be entitled as a matter of right to subscribe for or purchase or receive any part of any new or additional issue of shares of stock of any class, or of securities convertible into shares of stock of any class, whether now hereafter authorized or whether issued for money, for consideration other than money, or by way of dividend.

Effective immediately upon the filing and effectiveness of this Certificate of Amendment of the Certificate of Incorporation (the "Filing Date") and without any further action on the part of the Corporation or any stockholder, each ten (10) shares of Common Stock of the Corporation that are issued and outstanding on the Filing Date shall be reverse split and combined into one (1) share of Common Stock of the Corporation (the "Reverse Stock Split"). The Reverse Stock Split shall be effected on a certificate-by-certificate basis. All share and per share amounts set forth in this Certificate have been revised to reflect the Reverse Stock Split, and, accordingly, no further adjustment pursuant to this Certificate shall be made as a result of the Reverse Stock Split."

3. This Amendment of the Corporation's Certificate has been duly authorized and adopted by the Corporation's Board of Directors and stockholders in accordance with the provisions of Section 242 of the Delaware General Corporation Law.

Exhibit 4.1

NUMBER

INNOVATE
BIOPHARMACEUTICALS

SHARES

CUSIP 45782F 10 5

SEE REVERSE FOR
CERTAIN DEFINITIONS

INCORPORATED UNDER THE LAWS OF DELAWARE

AUTHORIZED: 350,000,000 COMMON SHARES,
$0.0001 PAR VALUE PER SHARE

THIS CERTIFIES THAT SPECIMEN

is the owner of

Fully Paid and Non-Assessable Common Stock, $0.0001 Par Value of

INNOVATE BIOPHARMACEUTICALS, INC.

transferable on the books of this Corporation in person or by attorney upon surrender of this Certificate duly endorsed or assigned. This Certificate and the shares represented hereby are subject to the laws of the State of Delaware, and to the Articles of Incorporation and the Bylaws of the Corporation, as now or hereafter amended. This Certificate is not valid until countersigned by the Transfer Agent.

IN WITNESS WHEREOF, the Corporation has caused this Certificate to be signed by the facsimile signatures of its duly authorized officers and to be sealed with the facsimile seal of the Corporation.

Dated:

/s/ Jay Madan
PRESIDENT

/s/ Kendyle Woodard
SECRETARY

[INNOVATE BIOPHARMACEUTICALS, INC., CORPORATE SEAL OF DELAWARE]

COUNTERSIGNED AND REGISTERED:
CORPORATE STOCK TRANSFER, INC.
TRANSFER AGENT AND REGISTRAR

By

Authorized Signature

(REVERSE SIDE)

INNOVATE BIOPHARMACEUTICALS, INC.

CORPORATE STOCK TRANSFER, INC.

TRANSFER FEE: AS REQUIRED

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM - as tenants in common
TEN ENT - as tenants by the entireties
JT TEN - as joint tenants with right of survivorship and not as and not as tenants in common

UNIF GIFT MIN ACT _Custodian_____
(Cust) (Minor)
under Uniform Gifts to Minors Act

Act_____
(State)

Additional abbreviations may also be used though not in the above list.

PLEASE INSERT SOCIAL SECURITY OR OTHER
IDENTIFYING NUMBER OF ASSIGNEE

FOR VALUE RECEIVED, _____ hereby sell, assign and transfer unto

---

PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS INCLUDING POSTAL ZIP CODE OF ASSIGNEE

_____ Shares
of the Common Stock represented by the within Certificate and do hereby irrevocably constitute and appoint

_____ Attorney to transfer
the said stock on the books of the within-named Corporation, with full power of substitution in the premises.

Dated: _____ 20_____

Signature: X _____

Signature(s) Guaranteed:

Signature: X _____

THE SIGNATURE(S) TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME(S) AS WRITTEN UPON THE FACE OF THE CERTIFICATE

Exhibit 10.1

SUBLICENSE AGREEMENT

This Sublicense Agreement ("Agreement") effective as of February 19, 2016 ("Effective Date") is made by and between Alba Therapeutics Corporation, a Delaware corporation ("Alba"), having an address at 100 International Drive, 23rd Floor, Baltimore, MD 21202, and Innovate Biopharmaceuticals, Inc., a Delaware corporation, having an address at 8601 Six Forks Road, Suite 400, Raleigh, NC 27615 ("Innovate").

WHEREAS, Alba and Innovate are parties to an Option Agreement, dated October 7, 2015, as amended, in which Alba granted an exclusive option to Innovate for the purchase of Alba's assets relating to Larazotide acetate and related compounds, which option was exercised by Innovate on January 15, 2016.

WHEREAS, in lieu of entering into an asset purchase agreement, Alba and Innovate elected to enter into a license arrangement with respect to substantially all of Alba's assets (the "Assets") and an accompanying sublicense arrangement with respect to that certain Restated Master License Agreement, dated as of July 1, 2005, by and between Alba and the University of Maryland, Baltimore, a copy of which is attached hereto as Exhibit A (the "UM License Agreement").

WHEREAS, as of equal date hereof, Alba and Innovate shall enter into that certain License Agreement (the "Primary License Agreement"), pursuant to which, among other things, Alba shall grant to Innovate, and Innovate shall accept, an exclusive license to the Assets.

WHEREAS, subject to certain conditions set forth in the Primary License Agreement, upon completion by Innovate of certain clinical milestones, Alba desires to sell, and Innovate desires to purchase, the Assets and the UM License pursuant to an asset purchase agreement incorporating terms mutually agreed upon therein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth below, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Alba and Innovate hereby agree as follows:

I. DEFINITIONS

A. "Licensed Field" shall mean all fields.

B. "Licensed Product(s)" shall mean any pharmaceutical composition containing, consisting of, or comprising: (i) [***]; (ii) larazotide, including any salt or ester thereof including larazotide acetate; and (iii) to the extent not contemplated by the preceding clauses (i)-(ii), a compound for treating or preventing a condition, including but not limited to Celiac Disease, or its use in treatment or prevention of a condition, including but not limited to Celiac Disease, where the compound or method of use is covered by an issued patent.

C. "Patent Rights" shall mean Alba's interest in the patents and patent applications related to the Licensed Product, as further itemized in Exhibit B, including (i) patents and patents that may issue from the applications, (ii) all continuations, continuations-in-part, divisions, reissues, re-examinations or extensions of the foregoing, and (iii) and foreign counterparts of any of the foregoing.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

II. GRANT; SUBLICENSES

A. Alba hereby grants to Innovate, and Innovate accepts, an exclusive worldwide sublicense under the UM License Agreement with respect to the Patent Rights, to conduct research and development and to make, have made, use, lease, offer to sell, sell and import the Licensed Products within the Licensed Field, anywhere in the world, for the term of this Agreement.

B. Innovate hereby agrees to be bound by, and comply with all obligations under, the terms of the UM License Agreement as it pertains to Licensed Products, which terms are incorporated by reference herein and made a part of this Agreement, and to satisfy Alba's obligations and those of its sublicensees per the terms of the UM License Agreement, as if Innovate were the original licensee (i.e. "Company") thereunder.

C. In addition to and not in lieu of the provisions of Section II.B above, the provisions and terms of Article 16 (Claims, Indemnification and Insurance) of the UM License Agreement shall be read *mutatis mutandis* as if Alba were the licensor thereunder (i.e. "UM", "UM Party" and "UM Parties") and Innovate were the licensee thereunder (i.e. "Company") so as to offer Alba indemnification by Innovate and the benefits of insurance coverage; provided that the foregoing reference to Article 16 of the UM License Agreement shall not include Sections 16.01, 16.04(b) or 16.04(c) thereof.

D. In no event shall Innovate grant a sublicense under this Agreement without first obtaining Alba's written consent; provided that, in any sublicense for which Alba grants consent, Innovate shall remain responsible for the obligations of its sublicensees.

III. CONSIDERATION

A. At execution of this Agreement, Innovate will pay to Alba a one-time, non-refundable sublicense fee of One Hundred Thousand Dollars ($100,000.00).

IV. REPRESENTATIONS AND WARRANTIES

A. Alba hereby represents and warrants to Innovate that: (i) Alba has full legal right, power and authority to execute, deliver and perform its obligations under this Agreement; (ii) the execution, delivery and performance by Alba of this Agreement do not contravene or constitute a default under any provision of applicable law or of any agreement, judgment, injunction, order, decree, or other instrument binding upon Alba; and (iii) the officer of the Alba executing this Agreement has been authorized by the Alba's board of directors or governing body to execute this Agreement as the act of the Alba.

B. Innovate hereby represents and warrants to Alba that: (i) Innovate has full legal right, power and authority to execute, deliver and perform its obligations under this Agreement; (ii) the execution, delivery and performance by Innovate of this Agreement do not contravene or constitute a default under any provision of applicable law or of any agreement, judgment, injunction, order, decree, or other instrument binding upon Innovate; and (iii) the officer of Innovate executing this Agreement has been authorized by Innovate's board of directors or governing body to execute this Agreement as the act of Innovate.

V. TERM AND TERMINATION

A. This Agreement shall terminate upon the earlier of (i) the termination of the Primary License Agreement pursuant to the terms thereof, (ii) termination of the UM License Agreement pursuant to the terms thereof or (iii) an assignment of the UM License Agreement by Alba to Innovate upon an asset transfer agreement pursuant to Section 3.06 of the Primary License Agreement

VI. MISCELLANEOUS

A. This Agreement shall be governed, construed, and interpreted in all respects in accordance with laws of the State of Maryland without regard to the conflict of laws provisions of such.

B. This Amendment may be executed in counterparts with the same effect as if both parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument.

C. If any provision of this Agreement is held to be invalid, the other provisions will not be affected to the greatest extent possible consistent with the parties' intent.

[signature page to follow]

The parties have caused this Agreement to be executed by their duly authorized representatives on the dates indicated below.

INNOVATE:

INNOVATE BIOPHARMACEUTICALS INC.

By: /s/ Jay P Madan
Name: Jay P Madan
Title: President

ALBA:

ALBA THERAPEUTICS CORPORATION

By: /s/ Wendy Perrow
Name: Wendy Perrow
Title: CEO

[Signature Page to Sublicense Agreement]

EXHIBIT A

UM LICENSE AGREEMENT

[See attached]

RESTATED

MASTER LICENSE AGREEMENT
effective July 1, 2005
between
UNIVERSITY OF MARYLAND, BALTIMORE
and
ALBA THERAPEUTICS CORPORATION

TABLE OF CONTENTS

RESTATED

MASTER LICENSE AGREEMENT
for "Zonula Occludens Toxin and Zonulin and other Patents"

This Restated Master License Agreement ("Agreement") effective July 1, 2005 ("Effective Date") is made by and between the University of Maryland, Baltimore ("UM"), a constituent institution of the University System of Maryland, a public corporation and an instrumentality of the State of Maryland, having an address at 520 West Lombard Street, East Hall, Room 200, Baltimore, Maryland 21201, and Alba Therapeutics Corporation, a corporation of Delaware, with its principal place of business at 2400 Boston St., Suite 310, Baltimore, MD 21224 ("Company").

ARTICLE 1. BACKGROUND

1.01 As a public research and education institution, UM is interested in licensing Patent Rights (as defined below) to Company in order to benefit the public through the development and marketing by Company of new and useful tools, methods and commercial products.

1.02 Valuable inventions ("Inventions") comprised of the Patent Rights identified in Exhibit A-1, and generally known as "Zonula Occludens Toxin and Zonulin," have been made by Inventors (as defined below).

1.03 Subject to certain rights retained by the federal government in inventions resulting from federally supported work, under UM policy or by assignment of rights from prior owners UM owns all right, title, and interest in and to the Inventions, which has been confirmed by the execution of assignments to UM from the Inventors or by assignment from a prior owner; provided, however, that UM is the joint owner with ISS (defined below) of one Invention, as indicated in Exhibit A-1.

1.04 Company desires to obtain a license to the Patent Rights as set forth in this Agreement.

ARTICLE 2. DEFINITIONS

In this Agreement, the following terms have the meanings set forth in this Article.

2.01 "Affiliate": Any entity that directly or indirectly controls, is controlled by, or is under common control with Company. "Control" means the right to exercise more than 50% of the voting rights of a controlled corporation, limited liability company, or partnership, or the power to direct or cause the direction of the management or policies of any other controlled entity.

2.02 "Company Data": Information arising out of or resulting from use of the Patent Rights made by one or more employees, agents or consultants of, or owned by, Company or Company's Affiliates or Sublicensees, including, without limitation, documents, drawings, sketches, models, designs, data, memoranda, tapes, records, formulae and algorithms, in hard copy form or in electronic form.

2.03 "Company Facilities": All funds, offices, laboratories, computers, equipment, computer networks, animal care facilities, and libraries, owned or controlled by Company or an Affiliate of Company, or utilized for Company pursuant to a contract between Company and a Third Party. Company Facilities includes, without limitation, space in Building One of the UMB BioPark which is leased by Company.

2.04 “Company Improvement”: Any Improvement (a) having as inventors, under U.S. patent law, only one or more Company Personnel, none of whom used UM Facilities in the work that resulted in the Improvement; or (b) otherwise owned by Company or a Company Affiliate pursuant to agreement with a Third Party.

2.05 “Company Personnel”: Employees, agents or consultants of Company or Company’s Affiliates; also, members of Company’s scientific advisory board. Company Personnel includes UM Personnel while acting as Company Personnel, and not as UM Personnel, pursuant to a written agreement between Company and the individual(s) approved in writing by UM before services were performed for Company.

2.06 “Confidential Information”: Information relating to the subject matter of the Patent Rights which has not been made public and includes, without limitation, any documents, drawings, sketches, models, designs, data, memoranda, tapes, records, formulae and algorithms, given orally, in hard copy form, or in electronic form, which Company receives from UM or UM Personnel, or UM or UM Personnel receives from Company.

2.07 “First Commercial Sale”: The initial transfer of a Licensed Product for compensation by Company, an Affiliate or a Sublicensee to a Third Party. Transfer of a Licensed Product for clinical testing occurring prior to the issuance of any required regulatory approval for sale does not constitute First Commercial Sale. Transfer of a Licensed Product for use as Research Tools does not constitute First Commercial Sale.

2.08 “Improvement”: An invention or discovery directly related to the Patent Rights in the Licensed Field which is or may be patentable or otherwise protected under law, and is reasonably necessary for the practice of the Patent Rights by Company or an Affiliate under this Agreement.

2.09 “ISS” means Instituto Superiore di Sanita, a joint owner of one of the inventions listed in Exhibit A-1, as indicated on that Exhibit.

2.10 “Joint Data”: Information arising out of or resulting from use of the Patent Rights made (a) by one or more employees, agents or consultants of, or owned by, Company or Company’s Affiliates, and (b) by one or more UM Personnel or agents or consultants of UM, or owned by UM, including, without limitation, documents, drawings, sketches, models, designs, data, memoranda, tapes, records, formulae and algorithms, in hard copy or electronic form.

2.11 “Joint Improvement”: Any Improvement having as inventors under U.S. patent law: (a) one or more Company Personnel and one or more UM Personnel; (b) one or more Company Personnel who used UM Facilities in the work that resulted in the Improvement; or (c) one or more UM Personnel who used Company Facilities in the work that resulted in the Improvement.

2.12 “Licensed Field”: The exclusive use of Patent Rights for all indications, applications, and uses including, without limitation, therapeutics, drug delivery products, research tools, research diagnostics, and clinical diagnostics.

2.13 “Licensed Product”: Any product that but for this license infringes any claims in the Patent Rights.

2.14 “Licensor Inventor(s)”: [***].

2.15 “Net Sales”: The gross sales revenues and fees invoiced by Company, an Affiliate or a Sublicensee to independent Third Party purchasers who are not Affiliates, for the sale of Licensed Products, less the sum of the following: (a) credits, allowances, discounts and rebates to, and charge backs from the account of, such Third Party purchasers for spoiled, damaged, out-dated, rejected or returned Licensed Products; (b) actual freight and insurance costs incurred in transporting such Liccnsed Products to such Third Party purchasers; (c) cash, quantity and trade discounts and other price reductions; (d) sales, use, value-added and other direct taxes incurred; (e) customs duties, surcharges and other governmental charges incurred in connection with the exportation or importation of such Licensed Products; and (f) the cost to Third Party purchasers of the devices for dispensing or administering such Licensed Products, as well as diluents or similar materials which accompany such Licensed Products as they are sold.

Net Sales do not include any resales of Licensed Product after its sale by Company, an Affiliate or a Sublicensee to a Third Party purchaser. In computing Net Sales, (1) no deductions from gross revenues and fees will be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed on the payroll by Company, its Affiliate(s) or Sublicensee(s), or for cost of collections, and (2) Licensed Products will be considered sold when invoiced.

2.16 “Patent Expenses”: All fees and charges of outside patent counsel related to Patent Rights that have not been reimbursed to UM, as well as all costs incurred by UM, or, where appropriate, Company, in connection with the preparation, filing, prosecution, issuance, reissuance, reexamination, interference, and maintenance of applications for patent or equivalent protection for the Patent Rights and UM Improvements.

2.17 “Patent Rights”: UM’s interest, as owner and as licensee (as indicated in Exhibit A-1) in:

(a) U.S. and foreign patent applications and patents listed in Exhibit A-1 as of the Effective Date;

(b) U.S. and foreign patent applications filed after the Effective Date that contain the same subject matter as the invention reports listed in Exhibit B, provided that the inventions claimed in such applications do not constitute Company Improvements;

(c) any divisions or continuations, or the foreign equivalent of these, of the U.S. and foreign patent applications described in (a) and (b);

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

(d) foreign patent applications which are filed as the foreign counterparts of the U.S. patent applications described in (a) and (b), and the foreign equivalent of divisions or continuations of such foreign patent applications;

(e) U.S. and foreign patents issuing from the applications described in (a), (b), (c) and (d); and

(f) any reissues, reexaminations or patent-term extensions, or the foreign equivalent of these, of U.S. and foreign patents described in (a) or (d).

2.18 "Sublicense Income": Consideration in any form received by Company or a Company Affiliate in consideration for the grant to any Sublicensee of a sublicense of the Patent Rights or Improvements (if licensed to Company). Sublicense Income will include without limitation any royalties on the Net Sales of Licensed Products, license signing fee, license maintenance fee, success fee, equity, and any similar consideration paid to Company or a Company Affiliate by or on behalf of the Sublicensee. Sublicense Income will exclude payment received in consideration for anything other than such sublicense, such as consideration for any equity or other investment in or extension of credit to Company, consideration for research or other services rendered by Company or Company Affiliates, or consideration for licenses(s) granted under technology other than the Patent Rights or Improvements.

2.19 "Sublicensee": A person or entity, including an Affiliate, to which Company sublicenses or transfers all or some of the Patent Rights.

2.20 "Third Party": Any entity or person other than UM, Company, an Affiliate or a Sublicensee.

2.21 "UM Affiliates": University of Maryland Medical System Corporation, faculty practice organizations of UM, the Baltimore Veterans Administration Medical Center, any constituent institutions of the University System of Maryland, and ISS.

2.22 "UM Data": Information in UM's possession received from Inventor(s) prior to the Effective Date which is directly related to Patent Rights in the Licensed Field and reasonably necessary for the practice of the Patent Rights by Company or an Affiliate or Sublicensee under this Agreement. UM Data includes, without limitation, documents, drawings, sketches, models, designs, data, memoranda, tapes, records, formulae and algorithms, in hard copy form or in electronic form.

2.23 "UM Facilities": All funds, personnel, offices, laboratories, computers, equipment, computer networks, animal care facilities, and libraries owned or controlled by UM or an Affiliate of UM, or utilized for UM work pursuant to a contract between UM and a Third Party.

2.24 "UM Improvement": An Improvement that, under U.S. patent law, (a) (i) has as inventors only one or more UM Personnel, none of whom used Company Facilities in the work that resulted in the Improvement, or (ii) otherwise is owned by UM pursuant to an agreement with a Third Party; and (b) is not restricted, as to licensing, by an option or license granted by UM under a sponsored research agreement with a Third Party.

2.25 "UM Personnel": Those Licensor Inventors employed by UM and its Affiliates, and students, trainees, and other persons working with Licensor Inventors, using UM resources, and subject to the USM Policy. UM Personnel includes Company Personnel who are acting as UM Personnel, and not as Company Personnel, pursuant to a written agreement between UM and the individual(s) approved in writing by Company before services were performed for Company.

2.26 "UM Rights in Improvements": UM Improvements and UM's joint interest in Joint Improvements.

2.27 "USM Policy" means the University System of Maryland Policy on Intellectual Property, effective July 1, 2002, as amended, or, as applicable, the predecessor Policy on Patents, effective May 31, 1990, as amended.

ARTICLE 3. GRANT OF LICENSE; OPTION

3.01 Subject to rights of the United States under grants to UM and pursuant to 35 U.S.C. Section 201 et seq. and all implementing regulations, and subject to Section 3.02, UM grants to Company, and Company accepts, an exclusive worldwide license under Patent Rights to conduct research and development and to make, have made, use, lease, offer to sell, sell and import the Licensed Products within the Licensed Field as defined in Section 2.13 above, for the term of this Agreement. This license includes the right to grant sublicenses consistent with this Agreement.

3.02 (a) UM specifically reserves the rights:

1. I. to practice, and permit UM Personnel and ISS to practice, under the Patent Rights, and to make and use the Licensed Products, and permit 1SS to make and use the Licensed Products, on a royalty-free basis solely for noncommercial research and education, and to license universities, colleges, and other noncommercial research or educational institutions to practice under the Patent Rights, and make and use the Licensed Products on a royalty-free basis solely for noncommercial research and education;
2. to provide information and material covered by the Patent Rights to universities, colleges and other noncommercial research or educational institutions, but only for research and educational purposes and uses, and not for any commercial purposes or uses; and
3. to permit UM Personnel to disseminate and publish scientific findings from research related to Patent Rights, subject to Section 7.05.

(b) UM agrees to offer Company the opportunity to negotiate for licenses of the Patent Rights outside the Licensed Field prior to entering into negotiation with other parties.

(c) UM agrees:

1. to provide Company with a complete list of any outstanding material transfer agreements ("MTA") relating to material (as defined in Section 1.4 of the form of MTA attached as Exhibit C) as of the Effective Date, and
2. subsequent to the Effective Date, to give Company 14 days notice prior to granting a research license or MTA involving the material or the Patent Rights. UM further agrees to use reasonable efforts to enforce all such research licenses or MTAs to their fullest extent. UM will use the form of MTA attached as Exhibit C to transfer materials after the Effective Date.

3.03 Company may transfer its rights to an Affiliate consistent with this Agreement, provided Company is responsible for the obligations of its Affiliate relevant to this Agreement, including the payment of royalties, whether or not paid to Company by its Affiliate.

3.04 Company may grant sublicenses consistent with this Agreement, provided Company is responsible for the obligations of its Sublicensees relevant to this Agreement, including the payment of royalties, whether or not paid to Company by its Sublicensees.

3.05 Company will identify its Affiliates and its Sublicensees under this Agreement to UM by name, address and field of sublicense (both as to geography and subject matter), and any other reasonable information necessary for UM to conduct a meaningful audit under Section 9.01, except that Company reserves the right to redact any and all confidential, technical and financial information that is nonessential to any such UM audit.

3.06 This Agreement confers no license or rights by implication, estoppel, or otherwise under any patent applications of UM other than Patent Rights within the Licensed Field, regardless of whether such patent applications or patents are dominant or subordinate to Patent Rights within the Licensed Field. Joint Improvements and UM Improvements are not considered part of Patent Rights unless added to Exhibit A-1 by proper amendment of this Agreement. Notwithstanding the foregoing, UM hereby represents that, without making an affirmative inquiry, soliciting a formal legal analysis or obtaining any other type of legal opinion, as of the Effective Date, it does not have any knowledge of patent claims, assertions or issued patents which are or purport to be dominant or subordinate to or otherwise may block Patent Rights identified in Exhibit A-1 within the Licensed Field. UM will notify Company promptly in writing of any patent claims, assertions or issued patents which are or purport to be dominant or subordinate to or otherwise may block Patent Rights within the Licensed Field of which UM becomes aware after the Effective Date of this Agreement, however, such obligation implies no burden on UM to perform a search and/or analysis in seeking these patent claims, assertions or issued patents. [***].

3.07 If Company intends to accept from Affiliates or Sublicensees anything of value in lieu of cash in consideration for any sublicense or other transfer of Patent Rights or Licensed Products, Company must notify UM in writing, within 30 days after the effective date of the Sublicensee or Affiliate agreement.

3.08 UM Improvements are owned by UM. Joint Improvements arc owned jointly by Company and UM. Company Improvements are owned by Company. UM has a nonexclusive option to negotiate with Company to enter into a nonexclusive, nontransferable license to UM to practice Company Improvements in any field of use for research and education but not for commercial purposes, and otherwise under those terms and conditions as may be agreed upon by UM and Company in a separate license agreement.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

3.09 (a) Subject to rights of other parties sponsoring research at UM, Company has an exclusive option to enter into an exclusive license agreement with UM for UM Rights in Improvements, within the Licensed Field, so long as (i) this Agreement is in effect, (ii) Company pays Patent Expenses for UM Rights in Improvements, and (iii) Company has not notified UM that Company declines to exercise its option. During the term of this option, UM Rights in Improvements will be subject to the same patent prosecution terms and conditions applicable to Patent Rights under Article 7 of this Agreement.

(b) 1. Company shall have an exclusive right of first negotiation with respect to UM Rights in Improvements (and UM agrees to negotiate with Company in good faith for at least 120 days with respect thereto) by giving written notice to UM within 60 days after Company receives written notice from UM of a UM Improvement or Joint Improvement in accordance with Section 3.11(a) below, or within 60 days after Company gives written notice to UM of a Joint Improvement in accordance with Section 3.11(b) below.

2. Company's exercise of the right of first negotiation initiates a negotiation period of 120 days. UM and Company will negotiate commercially reasonable terms including but not limited to royalties on Net Sales. The royalty rate will not exceed [***]%, provided that the UM Improvement or Joint Improvement did not result from research carried out in UM Facilities financed with qualified bonds within the meaning of Section 141 of the Internal Revenue Code unless in designated space available for private activity. If the research was carried out in space in UM Facilities financed with qualified bonds within the meaning of Section 141 of the Internal Revenue Code and not designated as space available for private activity, then the provisions of 3.09(b)(3) shall apply.

3. In order to comply with federal requirements associated with tax exempt financing of UM Facilities, if a UM Improvement or Joint Improvement results from research at UM Facilities sponsored by Company or an Affiliate, the royalty rate will not necessarily be set by terms of this license and will be determined following invention of a UM Improvement or Joint Improvement using a methodology to arrive at a fair market value determined without regard to research support provided by Company. The fair market value may be more than [***]%, less than [***]%, or [***]%. If UM and Company do not agree upon a fair market value within 30 days after Company exercises its right of first negotiation, then a mutually agreeable neutral party will determine the fair market value of the UM Improvement or Joint Improvement.

4. If any Licensed Product is claimed both by (a) Patent Rights and (b) UM Improvements and/or Joint Improvements, then Company will only be responsible for paying [***].

(c) If the parties do not reach agreement under the right of first negotiation for any UM Improvement or Joint Improvement, and if UM thereafter determines to offer licenses to the UM Improvements or UM's joint interest in Joint Improvements to Third Parties on materially different economic terms than offered to or negotiated with Company, then UM, prior to offering such terms to a Third Party, shall offer such new terms to Company and negotiate in good faith with Company for at least 30 days to conclude an agreement on such terms.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

(d) Notwithstanding the foregoing, if Company determines in its sole discretion that the applicable UM Improvements or Joint Improvements are not of strategic interest to Company, Company may waive the foregoing 120-day negotiation period and /or Company's right of first negotiation, in whole or in part, in writing.

3.10 The terms of any license to Company for UM Rights in Improvements will include a reservation of a nonexclusive, non-transferable, irrevocable and royalty-free license to UM to practice UM Rights in Improvements in any field of use for research and education but not for commercial purposes.

3.11 (a) UM will report promptly to Company in writing each UM Improvement and each Joint Improvement disclosed to UM. This reporting requirement will be triggered by UM's determination that any invention disclosure concerns a UM Improvement or Joint Improvement. A copy of a provisional patent application filed by UM for the UM Improvement or Joint Improvement will satisfy this reporting requirement.

(b) Company will report promptly to UM in writing each Joint Improvement and each Company Improvement disclosed to Company. A copy of a provisional patent application filed by Company for a Joint Improvement or Company Improvement will satisfy this reporting requirement.

(c) If UM or Company determines that it has received a disclosure from an inventor which does not relate to a Joint Improvement, and relates only to an Improvement owned solely by the other party, then the party that received the disclosure will not file a provisional application, will forward the disclosure immediately to the other party as confidential information, and will counsel the disclosing inventor to contact the other party.

(d) Either party, or both, may file a provisional application on an Improvement that may be a Joint Improvement prior to the parties having discussed inventorship and ownership issues. If UM or Company determines that it has received a disclosure involving one or more inventors who is employed by or affiliated with the other party, or who is employed by both parties, then the party which received the disclosure will notify the other party immediately that a disclosure has been made so that the other party may request a disclosure from its personnel. As soon as a provisional application is filed by UM or Company, and disclosed to the other party, the parties will confer to determine inventorship and whether the disclosed improvement is owned by one party or is a Joint Improvement. The parties will determine (i) which of them will file a provisional application if no application has been filed; (ii) if two applications have been filed, which will be withdrawn; or (iii) if one of them has filed an application which should have been filed by the other, in which case the filing party will assign the application to the other party.

(e) If there is a dispute between the parties as to ownership of an improvement, or as to identification of inventors, and/or whether the inventors were acting as Company Personnel or UM Personnel, the parties will refer the matter to a mutually agreeable, neutral third party for binding resolution. Normally the third party will be a partner in a national or regional intellectual property law firm that does not represent either party as to any other matter.

(f) The parties recognize a common legal interest in the prosecution of patent rights subject to this Agreement, and the prosecution or defense of interferences and infringement claims. The Parties have determined that a mutual defense agreement is not necessary to establish attorney-client privilege with respect to communications among the Parties and patent counsel engaged by one or both of them with respect to patent issues in which the Parties have mutual interest. Notwithstanding the foregoing, the Parties reserve the right to enter into joint defense agreements, commonality of interest agreements or any other agreements that are deemed appropriate, and the entry of the Parties into such agreements shall not be considered an admission that such agreements are necessary to preserve the confidentiality and privileged nature of attorney-client communications. Each Party shall assert, and instruct its counsel to assert, the confidentiality and privileged nature of communications among the Parties and their counsel as contemplated by this Agreement as well as prior communications among the Parties and their counsel with regard to matters that are the subjects of this Agreement, so long as there is mutuality of interest. Neither Party is obligated by this Agreement to share privileged material with the other Party. UM and Company do not intend to waive any legal privilege or other privilege created by law as a result of sharing with each other the communications between each of them and its patent counsel, whether or not UM and Company are using the same patent counsel or separate counsel.

(g) For business reasons, UM and Company may be represented by the same patent counsel, which counsel will be instructed that it represents both parties so that the attorney client relationship privilege attaches to counsel's communications with both parties. In this event, the counsel chosen may not represent either party as to business negotiations between them, or as to any dispute between them. If there is a dispute between the parties as to prosecution of any patent application, either party may require that each party secure separate legal counsel for any application in dispute, with neither party being represented as to that application by the counsel originally retained to prosecute it on behalf of both parties.

ARTICLE 4. COMPANY RESPONSIBILITIES

4.01 Company will use its commercially reasonable efforts to bring one or more Licensed Products to market in each country in which Patent Rights are licensed through a diligent program for exploitation of the Patent Rights within the Licensed Field. Company's efforts must satisfy the following milestones:

(a) [***].

(b) [***].

(c) [***].

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

(d) Company will use commercially reasonable efforts to meet the following specific diligence milestones:

1. [***];
2. [***];
3. [***];
4. [***]; and
5. [***].
6. [***].
7. [***].

4.02 Company agrees that any Licensed Products for use or sale in the United States will be manufactured substantially in the United States in accordance with the requirements of 35 U.S.C. Section 204 and 37 CFR 401.14(a)(i). in the event Company determines that compliance with this obligation is commercially impracticable, UM agrees that it will apply for a waiver of such obligation from the United States Government. In agreements with Affiliates and Sublicensees, Company will pass through this obligation. Company will use its best efforts to enforce this obligation and will promptly advise UM of any known violations, or charges of violations, of this obligation.

4.03 The use and disclosure of technical information acquired pursuant to this Agreement and the exercise of Patent Rights granted by this Agreement are subject to the export, assets, and financial control regulations of the United States of America, including, without limitation, restrictions under regulations of the United States that may be applicable to direct or indirect re-exportation of such technical information or of equipment, products, or services directly produced by use of such technical information. Company is responsible for taking any steps necessary to comply with such regulations.

4.04 Company will ensure that “Patent Pending” or the Patent Rights patent number or both appears on all Licensed Products, their labels or their packaging.

4.05 Company represents that, as of the Effective Date, it and its Affiliates qualify as a small business concern that meets the size standards set forth in 13 CFR Part 121 to be eligible for reduced patent fees under 37 C.F.R. 1.27. Company must provide written notification to UM immediately upon Company’s learning that Company and its Affiliates no longer qualify as a small business concern or immediately after Company sublicenses any part of the Patent Rights to an entity that does not qualify as a small business concern.

ARTICLE 5. CONSIDERATION: PAYMENTS

In consideration of the license granted to Company of the Patent Rights listed in Exhibit A-1 as of the Effective Date:

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

5.01 (a) Company will pay to UM the following [***] milestone payments for Licensed Products brought to market by Company, its Affiliates or its Sublicensees:

1. [***]

2. [***]

3. [***]

(b) [***].

(c) [***].

5.02 [***].

5.03 (a) [***]

(b) [***].

5.04 (a) [***].

(b) [***].

5.05 For Licensed Products sold in a calendar year by a Sublicensee that is not an Affiliate, Company will pay to UM:

(a) [***];

(b) [***];

(c) [***];

(d) [***].

(e) [***].

(f) Non-cash consideration from a Sublicensee may be accepted by Company or an Affiliate provided that Company notifies UM within 30 days after such consideration is rendered. If a Sublicensee's license agreement provides fair market value in cash or non-cash consideration for the Sublicensee's use of Patent Rights and, in addition, provides that Company or an Affiliate will receive other funds for separate consideration [***]. The fair market value of non-cash consideration is the greater of the fair market value determined as of the effective date of the sublicense agreement or the date of transfer of the non-cash consideration to the Company or Affiliate. Notice required by this paragraph is in addition to the notice required under Section 3.07.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

(g) For any non-cash Sublicense Income paid in securities or other assets, Company will pay UM the royalty in kind by transferring and delivering to UM the required percentage of such securities or other assets within sixty (60) days of Company or Company Affiliate receiving such securities or other assets; provided, however, that if Company or Company Affiliate cannot transfer and deliver such securities or other assets within such period without violating an applicable law, regulation or other legal requirement, or the terms of any agreement or other arrangement with a Third Party (including the Sublicensee), then Company or Company Affiliate will transfer and deliver such securities or other assets to UM on its first opportunity to do so. Any income received by Company or a Company Affiliate during the period of delay which is allocable to the securities or other assets due to UM also will be transferred to UM at the time the securities or other assets are so transferred.

(h) For non-cash Sublicense Income that cannot be quantified and shared as contemplated by Section 5.05(g), the parties will negotiate in good faith to arrive at a mutually agreeable solution under which UM will receive the required percentage of the value received by Company and/or Company Affiliates as Sublicense Income. Disputes over the required percentage to be shared with UM that cannot be resolved through the dispute resolution process under Article 18 will be referred to a mutually agreed national accounting firm or other independent expert for resolution.

5.06 (a) In the event that Company or an Affiliate is required to license one or more technologies of a Third Party in order to conduct research and development and to make, have made, use, lease, offer to sell, sell or import Licensed Products or to practice or otherwise make use of the Patent Rights, and is required to pay a royalty to one or more Third Parties, Company or its Affiliate may deduct from royalties due to UM [***]% of the royalty paid to the Third Party(ies), but in no event may the royalties due to UM be reduced by more than [***]% as a result of licenses from Third Parties.

(b) In sublicense agreements, Company will not permit Sublicensees that are not Affiliates to deduct more than [***]% of royalties due to Company as a result of licenses from Third Parties.

5.07 (a) No multiple fees or royalties are payable because any Licensed Product, its manufacture, use, sale, or lease is or will be covered by more than one patent application or patent licensed under this Agreement as part of Patent Rights.

(b) The aggregate reduction of royalties on Net Sales as a result of applicability of Sections 5.05, 5.06, and 5.07 will not exceed [***] % of royalties as calculated with no reduction of royalties on Net Sales as permitted by these Sections.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

5.08 (a) Royalties are payable from the country in which they are earned and are subject to foreign exchange regulations then prevailing in the country. Royalty payments must be paid to UM in United States Dollars by check(s) drawn to the order of UM or by electronic funds transfers to an account designated by UM. To the extent sales may have been made by Company, its Affiliates or Sublicensees in a foreign country, those royalties will be determined first in the currency of the country in which the royalties are earned, and then converted to their equivalent in United States Dollars. The buying rates of exchange for converting the currencies involved into the currency of the United States quoted by the Morgan Guaranty Trust Company of New York, New York, [***], will be used to determine any such conversion. Company will bear any loss of exchange or value or pay any expenses incurred in the transfer or conversion to U.S. dollars.

(b) To the extent that statutes, laws, codes, or government regulations (including currency exchange regulations) prevent or limit royalty payments to UM by Company, its Affiliates or its Sublicensees with respect to Net Sales received in any country, Company will render to UM annual reports of sales of Licensed Products in such country. All monies due and owing UM as provided in the annual reports at UM's option (1) will be deposited promptly by Company, its Affiliates or its Sublicensees, as the case may be, in a local bank in such country in an account to be designated by UM in writing, or (2) will be paid promptly to UM or deposited in its account, as directed in writing by UM in any other country where the payment or deposit is lawful under the currency restrictions.

5.09 If Company sells Licensed Products to its Affiliates or Sublicensees for subsequent resale, no royalty will be due on the sales to Affiliates or Sublicensees, but royalty will be calculated and paid on the resale of the Licensed Product to a Third Party. If Company sells Licensed Products to a Third Party in a non-ann's length transaction, and the Licensed Products are not subsequently resold, the selling price of the Licensed Products to the Third Party is deemed to be the selling price that would have been received in an arm's length transaction, based on sales of products of similar quantity and quality on or about the time of such transaction, or, in the absence of such sales, based upon reasonable pricing practices in Company's industry.

5.10 All payments required by this Article 5 with respect to Net Sales, milestones, or other consideration received during a calendar year are due on the date the annual report for that year, as required by Section 9.02, is due to UM, i.e., the 90th day after the end of the calendar year for which payment is due. Interest is due on any payments to UM required by any Section of this Agreement that are more than 30 days late. Also, interest is due on the amount of any underpayment of royalties or other amounts payable to UM under this Agreement. The interest rate is the prime rate plus [***] percent simple interest per annum accruing from the due date.

5.11 If Joint Improvements and/or UM Improvements are added to Patent Rights by amendment of Exhibit A-1, the amendment will specify whether and how the terms of Sections 5.01 to 5.08 are applied to the Patent Rights. Except as provided in 3.09(b), there is no presumption that Joint Improvements or UM Improvements will be licensed upon the terms and conditions originally provided in those Sections.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

5.12 (a) UM has received [***], for and in consideration of this Agreement and without payment of any further consideration by UM.

(b) [***].

(c) [***].

(d) Company acknowledges that UM: [***].

(e) [***].

(f) [***].

ARTICLE 6. DATA

6.01 Company Data is owned by Company. Joint Data is owned jointly by Company and UM. UM Data is owned by UM.

6.02 Nothing herein shall be construed to require Company to disclose or deliver to UM or any Third Party Company Data related only to a Company Improvement unless one of the inventors of that Company Improvement is both Company Personnel and UM Personnel. In such cases, Company will disclose the Company Improvement to UM as provided below, and will disclose the Company Data as needed for UM and Company to determine inventorship and ownership of the improvement.

6.03 Nothing herein shall be construed to require either party to disclose or deliver to the other party any information or communication that is considered by the disclosing party to be protected by the attorney-client privilege, or is considered by the disclosing party to be attorney work product, without the express written consent of the disclosing party, or the execution of an agreement consistent with Exhibit F.

6.04 To the extent permitted by law, UM will keep any and all Company Data and Company Improvements, howsoever disclosed to or acquired by UM, confidential in accordance with Article 8, and Company will keep UM Data and Joint Data confidential in accordance with Article 8 if so requested by UM. Any information that would identify human research subjects or patients will be maintained confidentially by UM and Company to the extent permitted by law. Joint Data which may result from research carried out by UM personnel will be subject to Section 7.05. Any part of Joint Data which is Company Confidential Information will be subject to Article 8.

6.05 While this Agreement is in effect and Company is pursuing commercialization efforts, Company will have the right to use UM Data and Joint Data in and for regulatory filings on behalf of Company or its Affiliates and UM will have the right to use Joint Data for noncommercial research purposes. If this Agreement is terminated, UM will have (a) the exclusive right to use and publish UM Data and (b) the non-exclusive right to use and publish Joint Data, for noncommercial research purposes, and for regulatory filings related to Patent Rights, both rights being subject to Section 7.05 and, with respect to protection of Company Confidential Information, Article 8.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

ARTICLE 7. PATENT PROSECUTION AND PUBLICATIONS

7.01 (a) UM is responsible for filing any patent applications for the Patent Rights, and UM Improvements. Company is responsible for filing any patent application for Joint Improvements unless Company and UM agree in writing that UM will assume such responsibility for any or all of Joint Improvements. Company is responsible for the filing, prosecution, and maintenance of patent applications for Company Improvements.

(b) The scope of patent coverage within Patent Rights, UM Improvements, or Joint Improvements will not be significantly modified by the party responsible for filing patent applications without prior review of the other party. UM will not significantly limit the scope of patent coverage within Patent Rights or UM Improvements without the prior written consent of Company. Company will not significantly modify or limit the scope of patent coverage within Joint Improvements without the prior written consent of UM. If approval is requested by notice in writing, and is neither given nor denied in writing within 10 business days after the date notice is received, approval will be deemed given.

(c) With respect to Patent Rights and UM Improvements, UM will invoice Company for Patent Expenses incurred by UM after the Effective Date with respect to U.S. patents and patent applications. Company will pay the invoice in full to UM within 30 days after the date of UM's invoice. Company's failure to pay an invoice on time will result in interest charges in accordance with Section 5.10 as well as loss of input into patenting decisions until such time as Company pays all outstanding invoices for Patent Expenses and accrued interest. Additionally, Company's failure to pay an invoice and accrued interest within 90 days after date of invoice will result in termination of Company's option rights under Section 3.09.

(d) Further, with respect to Patent Rights and UM Improvements, and with respect to the filing and prosecution of foreign patent applications specified by Company in accordance with Section 7.04, Company will pre-pay or directly pay charges and fees, including attorneys' fees, or will reimburse UM for those charges and fees, at UM's option.

(e) With respect to Joint Improvements, Company may choose outside patent counsel subject to UM's approval, which approval must not be withheld or delayed unreasonably. If UM has not approved or diasapproved patent counsel within 10 business days of notice of a request for approval, UM's approval shall be deemed given. Fees incurred by Company for patent action on Joint Improvements are Company's sole responsibility.

(f) If Company chooses not to file a patent application for a Joint Improvement, or chooses to abandon an application for a Joint Improvement, it will give UM 30 days prior notice, and UM may continue prosecution of a patent application at its own expense if it chooses. If UM chooses not to file, or to abandon, a patent application as described in this section, then Company's license of UM's interest in the Joint Improvement will terminate as of the date UM gives notice of its decision.

(g) If UM and Company do not agree on actions relating to scope of patent coverage for any of Patent Rights, UM Improvements or Joint Improvements, UM may terminate immediately Company's right to prosecute the patent application(s) involved, and in such case UM may continue prosecution, using its own, independent counsel, and at Company's expense, unless Company notifies UM that Company chooses to terminate its license of the Patent Rights, UM Improvements or Joint Improvements involved.

(h) Determination that UM Personnel or Company Personnel are inventors of an improvement. For purposes of this Agreement, all UM Personnel or Company Personnel who are considered inventors of an Improvement under United States patent law will be listed as inventors of that Improvement. Only inventorship under U.S. law will be considered in determining whether an Improvement is a Company Improvement, Joint Improvement or UM Improvement. The Parties recognize that the patent laws of countries where patent applications are filed may follow rules of inventorship that differ from U.S. patent law.

7.02 (a) UM will invoice Company for Patent Expenses incurred by UM prior to the Effective Date that have not been reimbursed by Third Parties and arc identified in Exhibit D, and Company will pay the invoice in full to UM not later than September 1, 2005.

(b) If Company does not license UM Improvements, Company will have no obligation under Section 3.09(a) to pay Patent Expenses related to the UM Improvements or Joint Improvements incurred by UM for patent filing and prosecution activities occurring more than 60 days after Company's option is terminated or expires as provided in Section 3.09. UM will act in good faith to minimize the Patent Expenses incurred between receipt of notice and the end of the 60 day period.

(c) If this Agreement is terminated for any reason other than expiration in accordance with Section 11.01, Company will have no obligation to pay Patent Expenses related to Patent Rights or UM Improvements incurred by UM for patent filing and prosecution activities occurring more than 60 days after termination. UM will act in good faith to minimize the Patent Expenses incurred between receipt of notice of termination and the end of the 60 day period.

7.03 Company and UM will cooperate to limit the Patent Expenses while making reasonable efforts to have the Patent Rights cover all items of commercial interest and importance. Company and UM will cooperate to define the scope and content of U.S. and foreign patent applications to be filed under Patent Rights. UM is solely responsible for making decisions regarding scope and content of U.S. and foreign applications to be filed under Patent Rights and UM Improvements and prosecution of the applications. Company is solely responsible for making decisions regarding scope and content of U.S. and foreign applications to be filed under Joint Improvements and prosecution of the applications. The responsible party will give the other party a reasonable opportunity to advise the responsible party with respect to their respective patent applications. The parties will cooperate with each other in the prosecution, filing, and maintenance of their respective patent applications. The parties will advise one another promptly as to all material developments with respect to the applications. Copies of all papers received and filed in connection with prosecution of applications will be provided promptly to the other party to enable it to advise the responsible party thereon.

7.04 (a) UM has disclosed to Company or Company has disclosed to UM the patent applications and patents in effect for the Patent Rights listed in Exhibit A-1. With respect to patent application Serial Numbers [***], or further patent applications related to invention reports listed in Exhibit B, or UM Improvements, UM will file patent applications in [***], and additional countries specified by Company in accordance with this section. Company will specify in writing to UM the additional foreign countries in which patent applications are to be filed and prosecuted. Company will specify such additional countries no later than 60 days before the national phase filing deadline for the pertinent patent application. UM or Company will cause foreign filings to be made by patent counsel. If Company gives at least 60 days prior written notice to UM, Company may elect to discontinue support for Patent Expenses in any country other than [***]. Company will be responsible for reasonable Patent Expenses incurred in that 60 day period with respect to the country or countries where Company is ceasing support. From and after UM's receipt of Company's notice, Company's exclusive rights in Patent Rights and UM Rights in Improvements will become non-exclusive with respect to the country or countries where Company is ceasing support, and Company will execute such documents as reasonably may be requested by UM to confirm conversion of Company's rights.

(b) UM may elect to file and prosecute patent applications, solely at its own expense, in foreign countries not listed in Section 7.04(a) or not specified by Company. If UM so elects, Company will have no right to approve UM's patent counsel, and no license rights with respect to Patent Rights and UM Improvements in those countries, and no option rights with respect thereto in those countries, unless otherwise agreed to by the parties in writing.

7.05 In order to safeguard Patent Rights, UM Improvements and Joint Improvements, UM will request that UM Personnel not disseminate or publish any results or otherwise publicly disclose the results of research performed by UM Personnel relating to the Patent Rights within the Licensed Field and subject to the license(s) granted to Company under this Agreement unless any materials containing those results are first submitted to UM and, by UM, to Company, for review, comment, and consideration of appropriate patent action. UM will inform UM Personnel working with Patent Rights that they are required to submit materials relating to a planned written publication or other public disclosure to UM for review at least 90 days prior to the date of the planned submission for written publication or other disclosure. UM will promptly advise Company of any proposed publications or public disclosures reported to UM and will furnish Company a copy of the proposed publication or public disclosure as soon as submitted to UM. Company will advise UM within 30 days after Company's receipt of the materials whether patent applications will be filed in connection with obtaining or maintaining Patent Rights related to the materials submitted by UM. UM will advise UM Personnel that they must delay written publication or public disclosure up to a maximum of 60 days after the date Company receives the materials to enable UM or Company to file, at Company's expense, any patent applications recommended by Company.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

ARTICLE 8. CONFIDENTIALITY

8.01 Knowingly or inadvertently, either party may disclose to the other certain Confidential Information. Disclosures by UM are deemed to refer to disclosures by any UM Personnel. Disclosures by Company are deemed to refer to disclosures by Company officers, directors, employees, consultants or agents. Confidential Information may be disclosed only in accordance with the provisions of this Article.

8.02 Except as hereafter specifically authorized in writing by the disclosing party, the receiving party will not disclose or use the Confidential Information for a period of [***] years after the date of receipt of Confidential Information.

8.03 These obligations of non-disclosure and nonuse do not apply to any Confidential Information which the receiving party can demonstrate by reliable written evidence:

(a) was generally available to the public at the time of disclosure to the receiving party; or

(b) was already in the possession of the receiving party at the time of the disclosure, other than pursuant to a confidential disclosure agreement between the parties and not due to any unauthorized act by the receiving party; or

(c) was developed by the receiving party prior to the disclosure; or

(d) the receiving party is required by law to disclose.

8.04 These obligations of non-disclosure and nonuse will not continue to apply to any Confidential Information which the receiving party can demonstrate by reliable written evidence:

(a) has become generally available to the public other than through a breach of this Agreement by the receiving party after disclosure;

(b) has been acquired by the receiving party on a nonconfidential basis from any third party having a lawful right to disclose it to the receiving party; or

(c) corresponds to information developed by the receiving party independent of and with no reliance upon the disclosing party's Confidential Information.

8.05 Each party will use that level of care to prevent the use or disclosure of the other party's Confidential Information as it exercises in protecting its own Confidential Information.

8.06 All Confidential Information will be clearly marked as confidential by the disclosing party and, if not in written or tangible form when disclosed, will be indicated as confidential upon disclosure and then summarized in writing and so marked as confidential within 30 days after disclosure to the receiving party.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

8.07 Notwithstanding the foregoing, Company, its Affiliates and its Sublicensees are permitted to disclose and use the Confidential Information to the extent reasonably necessary to exercise Company's license or sublicenses hereunder, or to comply with Federal reporting requirements, provided that any disclosure is made subject to written confidentiality restrictions consistent with those accepted by Company in this Agreement.

8.08 UM is an educational institution with standards and practices for protection of Confidential Information that differ from Company's standards and practices. By this Agreement UM undertakes reasonable efforts to enforce and protect to its fullest extent the confidentiality of Company's Confidential Information.

8.09 The records of UM are subject to the Maryland Access to Public Records Law (Title 10, Subtitle 6, Part III, State Government Article, Annotated Code of Maryland). This Agreement and its Exhibits (whether or not made part of this Agreement) are public records of UM under the Act. Reports to UM, as provided in Article 9, are public records of UM. Confidential Information of Company contained in this Agreement (and its Exhibits) and any other Confidential Information of Company received by UM is not subject to disclosure in response to a request under the Act if the Confidential Information is determined to be confidential financial information, confidential commercial information, or trade secret information as provided in Section 10-617(d) of the Act. Company asserts that any Confidential Information of Company provided to UM under this Agreement is confidential financial or commercial information, or trade secret information, not subject to disclosure under the Act. Unless UM determines on the advice of counsel that such position is not reasonable, UM agrees to assert this position in response to any request for public records applicable to Company's Confidential Information, and to promptly notify Company upon receipt of such a request.

8.10 Upon termination of this Agreement for any reason other than those set forth in Section 11.01 or a material breach by UM, Company will return to UM all material which is Confidential Information of UM, together with all copies and other forms of reproduction, except that a single archive copy may be kept in Company's legal files. Each party agrees that termination of this Agreement does not alter the [***] year obligation of confidentiality set forth in Section 8.02.

8.11 Upon termination of this Agreement for any reason other than those set forth in Section 11.01 or a material breach by Company, UM will return to Company all material which is Confidential Information of Company, together with all copies and other forms of reproduction, except that a single archive copy may be kept in UM's legal files. Each party agrees that termination of this Agreement does not alter the [***] year obligation of confidentiality set forth in Section 8.02.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

ARTICLE 9. REPORTS AND ACCOUNTING

9.01 During the term of this Agreement and for 5 years after its termination, Company will undergo annual audit by an independent public auditor. Company will keep, and will request each Affiliate and Sublicensee to keep, for at least four years after the close of each fiscal year of the organization in question, business records containing all the particulars that may be necessary to enable royalties payable to UM to be determined. Furthermore, the Company will permit Company records to be inspected at any time during regular business hours, upon reasonable notice, by an independent auditor appointed by UM for this purpose and acceptable to Company who will report to UM and Alba the amount of royalty or other compensation payable under this Agreement and the information used to calculate such royalty or compensation. This audit will be at UM's expense unless the audit shows an underpayment in amounts due to UM in relation to amounts paid to UM by [***]% or more for any annual period (as defined in Section 9.02) subject to audit, in which case the audit expense will be borne by Company.

9.02 Within 90 days after each December 31, Company will deliver to UM a true and accurate report, giving particulars of the business conducted by Company, its Affiliates and its Sublicensees, if any, in the preceding year that are pertinent to any accounting for royalties, fees, or other payments under this Agreement. These reports will be certified as correct by an authorized officer of Company and will include at least the following information for the reporting period:

(a) number of Licensed Products manufactured and sold by Company and by each Affiliate and each Sublicensee;

(b) total billings for Licensed Products sold by Company and by each Affiliate and by each Sublicensee;

(c) accounting for all Licensed Products used or sold;

(d) deductions as provided in Section 2.16;

(e) names and addresses of all Affiliates and Sublicensees of Company;

(f) facts indicating Company's diligence in accordance with Article 4.

9.03 With each report submitted in accordance with Section 9.02, Company must pay to UM the royalties, fees, or other payments due and payable under this Agreement for the annual period covered by the report. If no royalties, fees or other payments are due with the report, Company will so report.

9.04 UM is a unit of the government of the State of Maryland. Where Company, an Affiliate or a Sublicensee is required to report and withhold for taxation revenues paid to UM as licensor, Company, the Affiliate or the Sublicensee will assert that UM is exempt from the tax by virtue of its governmental status. If the Company, Affiliate, or Sublicensee nevertheless is required to withhold tax, any tax required to be withheld will be paid promptly by Company or its Affiliates and its Sublicensees for and on behalf of UM to the appropriate governmental authority, and Company will furnish UM with proof of payment of the tax together with official or other appropriate evidence issued by the competent governmental authority sufficient to enable UM to support a claim for tax credit or refund with respect to any sum so withheld. Any tax required to be withheld on payments by Company to UM will be an expense of and be borne solely by UM, and Company's royalty payment(s) to UM following the withholding of the tax will be decreased by the amount of such tax withholding. Company will cooperate with UM in the event UM elects to seek, at its own expense, administrative or judicial determination of tax exemption.

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9.05 During the implementation of the Business Plan described in Section 4.01, and if requested by UM, and subject to Company's right to fully preserve confidentiality of attorney work product and all material which is subject to attorney client privilege, Company will allow UM to inspect, at any time during regular business hours and upon reasonable notice, all Company correspondence to and from any pertinent U.S. regulatory agency and any foreign equivalent.

9.06 Company will report to UM the following dates within 60 days after occurrence: [***].

ARTICLE 10. INFRINGEMENT

10.01 UM and Company agree to notify each other promptly of each infringement or possible infringement of the Patent Rights of which either party becomes aware.

10.02 Company may (a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the Patent Rights licensed to Company; (b) in any such suit, enjoin infringement and collect for its use damages, profits, and awards of whatever nature recoverable for such infringement; and (c) settle any claim or suit for infringement of the Patent Rights. Company may not compel UM or ISS to initiate or join in any such suit for patent infringement. Company may request UM or ISS to initiate or join in any such suit if necessary to avoid dismissal of the suit. If UM or ISS is made a party to any such suit, Company will reimburse and indemnify UM and ISS for any costs, expenses, or fees which UM or ISS incurs as a result of its joinder. In all cases, Company agrees to keep UM reasonably apprised of the status and progress of any litigation.

10.03 If an infringement action or a declaratory judgment action alleging invalidity or non-infringement of any of the Patent Rights is brought against Company or raised by way of counterclaim or affirmative defense in an infringement suit brought by Company under Section 10.02, Company may (a) defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the Patent Rights; (b) in any such suit, ultimately enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and (c) settle any claim or suit for damages or a declaratory judgment involving the Patent Rights, including the granting of further licenses on sublicenses, provided that Company does not admit UM's or ISS's infringement or concede invalidation of any Patent Rights, without UM's or ISS's prior written consent, respectively. UM consent will not be unreasonably withheld. Company may not compel UM or ISS to initiate or join in any such suit. Company may request UM and ISS to initiate or join in any such suit if necessary to avoid dismissal of the suit. If UM or ISS is made a party to any such suit, Company will reimburse and indemnify UM or ISS for any costs, expenses, or fees which it incurs as a result of its joinder. In all cases, Company agrees to keep UM reasonably apprised of the status and progress of any litigation.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

10.04 (a) Company will not settle any action described in Section 10.02 or 10.03 without first notifying UM. In any action under Sections 10.02 or 10.03, the expenses of Company and UM, including costs, fees, attorney fees, and disbursements, will be paid by Company.

(b) Up to [***]% of such expenses may be credited against the running royalties payable to UM under Article 5 under the Patent Rights in the country in which such suit is filed. If [***]% of such expenses exceed the amount of running royalties payable by Company in any royalty year, the expenses in excess may be carried over as a credit on the same basis in succeeding royalty years. Any recovery of compensatory damages made by Company, through court judgment or settlement, will be treated as [***]. Any other recovery made by Company, through court judgment or settlement, [***]. Any remaining recoveries will [***].

10.05 UM will cooperate reasonably with Company in connection with any action under Sections 10.02 or 10.03. UM agrees to provide prompt access to all necessary documents and to render reasonable assistance in response to requests by Company.

10.06 UM has a continuing right to intervene in a suit initiated by Company under Section 10.02 or in a declaratory judgment action involving the Patent Rights brought against Company under Section 10.03. In either case, if UM chooses to intervene, UM will be responsible for its litigation expenses and will be entitled to all recoveries which it obtains for itself as a result of its intervention.

10.07 If Company desires to initiate a suit for patent infringement under Section 10.02, Company will notify UM in writing within 90 days after giving or receiving notice of infringement under Section 10.01. If Company fails to notify UM of its intent to initiate suit within the 90 day period or if Company notifies UM that it does not intend to initiate suit, UM may initiate suit at its own expense. In such case, UM is entitled to all recoveries from such action.

10.08 If an infringement action or a declaratory judgment action alleging invalidity or non-infringement of any of the Patent Rights is brought against Company or raised by way of counterclaim or affirmative defense in an infringement suit brought by Company as described in Section 10.02, Company will notify UM whether Company intends to respond in opposition to such legal action within 15 days after Company's receipt of notice of the filing of such action. If Company fails to notify UM of its intent to respond in opposition to such legal action within the 15 day period, or if Company notifies UM that it does not intend to oppose the action, UM may respond to the legal action at UM's expense. In such case, UM is entitled to all recoveries from such action.

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10.09 Company will cooperate reasonably with UM in connection with any action described in Sections 10.07 or 10.08. Company agrees to provide prompt access to all necessary documents and to render reasonable assistance in response to requests by UM.

ARTICLE 11. TERM AND TERMINATION

11.01 Unless sooner terminated in accordance with any of the succeeding provisions of this Article 11, this Agreement will continue in full force and effect until abandonment, disallowance, expiration, or invalidation of the last Patent Right anywhere which is licensed under this Agreement.

11.02 Should Company fail to pay UM any sum due and payable under this Agreement, UM may terminate this Agreement on 90 days written notice, unless Company pays UM within the 90 day period all delinquent sums together with interest due and unpaid. Upon expiration of the 90 day period, if Company has not paid all sums and interest due and payable, the rights, privileges, and licenses granted under this Agreement terminate.

11.03 Prior to the First Commercial Sale of a Licensed Product to a Third Party, Company is considered diligent with regard to development of a Licensed Product as long as Company updates and reports progress against the Business Plan and achieves the milestones described in Section 4.01 and as long as Company continues to provide the necessary financial and other resources which are required to maintain progress in accomplishing the Business Plan, as it relates to Licensed Products, and, conducts or enables others to conduct the activities required to maintain scheduled progress in accomplishing the Business Plan, as it relates to Licensed Products.

11.04 If UM declares Company not diligent in development or sales of Licensed Product based upon the criteria set forth in Section 11.03, then UM may terminate the portion of license or option grants under this Agreement upon 90 days written notice as may be appropriate with regard to the specific Licensed Field or subfield milestones set forth in Section 4.01(d). The withholding by a regulatory agency of marketing approval in spite of Company's diligent effort to obtain such approval may not be the basis for UM to declare Company not diligent.

11.05 In the event that Company, an Affiliate or a Sublicensee breaches Sections 3.03, 3.04, 3.05, 9.01, 9.02, 9.03, 10.04(a), 12.01, 15.02, 16.02, 16.03 or 19.02, or fails to make any payment to UM when due as provided by the terms above in this Agreement (except for Section 7.01(c), UM may terminate this Agreement upon 90 days written notice to Company. However, if the breach is corrected within the 90-day period and UM is reimbursed for all damages directly resulting from the breach, this Agreement will continue in full force and effect and UM will so notify Company in writing. Failure of Company to pay an invoice as required in Section 7.01(c) is grounds for immediate termination of this Agreement by UM if payment is overdue by [***] days or more.

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11.06 Company may terminate this Agreement at any time by giving UM 90 days written notice of termination, and upon payment to UM of all payments maturing through the effective date of the termination.

11.07 Expiration or termination of this Agreement does not relieve either party of any obligation for payment and reporting which arises before expiration or termination including obligations under Articles 5, 7 (but only for expenses incurred before termination) and 9. Articles 2, 10, 13, 14, 15, 16, 17, and 18 and Sections 5.12, 6.03, 11.08, 11.09 and 19.11 will survive expiration or termination. Article 8 and Sections 9.01 and 19.02 will survive expiration or termination and will expire in accordance with their terms. Other sections of this Agreement will be effective after expiration or termination where that intent is clear from the content of those sections.

11.08 Upon termination of this entire Agreement pursuant to Section 11.05, any Sublicensee not in default may seek a license directly from UM to practice Patent Rights within the licensed field set out in its sublicense and upon the consideration stated in its sublicense to the extent such consideration has not previously been paid to Company. UM will permit a Sublicensee not in default to continue use of Patent Rights for a period of up to 60 days ("the Continuation Term") after termination of this Agreement while UM and the Sublicensee negotiate, such license to be consistent with the terms of this Agreement subject to appropriate amendments of Article 5 and relevant definitions to substitute the consideration and field of use provisions from the sublicense. Should UM and the Sublicensee fail to agree upon an amendment within the Continuation Term, they will submit the definition and consideration provisions in dispute between them to commercial arbitration for resolution, and include the resulting provisions in a license. Prior to the Continuation Term, and in consideration of the opportunity to enter into a license agreement with UM, a Sublicensee seeking a license from UM must tender to UM a written agreement to pay [***].

11.09 Upon the expiration or termination of all or part of the license rights of Company under this Agreement, and at UM's request, Company will execute a document acknowledging the license rights that have expired or terminated.

ARTICLE 12. ASSIGNABILITY

12.01 Company may assign this Agreement to an Affiliate or to a successor to all or substantially all of Company's assets or business to which this Agreement relates. Company may not otherwise assign or transfer this Agreement without the prior written consent of UM, which will not be unreasonably withheld.

12.02 UM may assign this Agreement to a successor-in-interest but UM may not otherwise assign or transfer this Agreement without the prior written consent of Company, which will not be unreasonably withheld.

ARTICLE 13. APPLICABLE LAW; WAIVER

13.01 This Agreement is made and construed in accordance with the laws of the State of Maryland without regard to choice of law issues, except that all questions concerning the construction or effect of patents will be decided in accordance with the laws of the country in which the particular patent concerned has been granted.

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13.02 Company submits itself to the jurisdiction of the State courts of the State of Maryland and the Federal court in the Northern District of the State of Maryland for purposes of any suit relating to this Agreement, and further agrees that any action against UM relating to this Agreement will be initiated by Company only in a court of competent jurisdiction in Baltimore City, or Baltimore County, Maryland.

13.03 UM and Company waive their rights to trial by jury as to any litigation between them relating to this Agreement.

ARTICLE 14. INTEGRATION AND INTERPRETATION

14.01 This Agreement, together with any Exhibits specifically referenced and attached, embodies the entire understanding between Company and UM. There are no contracts, understandings, conditions, warranties or representations, oral or written, express or implied, with reference to the subject matter of this Agreement that arc not merged in this Agreement.

14.02 This Agreement is negotiated as an arm's-length business transaction. Draftsmanship will not be taken into account in construing the Agreement.

14.03 If any condition or provision in any Article of this Agreement is held to be invalid or illegal or contrary to public policy by a court of competent jurisdiction from which there is no appeal, this Agreement will be construed as though the provision or condition did not appear. The remaining provisions of this Agreement will continue in full force and effect.

ARTICLE 15. REPRESENTATIONS AND WARRANTIES

15.01 UM hereby represents that to the knowledge of the executing UM officer, as of the date of execution by the officer, (a) as confirmed by assignments from UM Personnel who are known to be among the Licensor Inventors, or by assignment from prior owners of certain Patent Rights, (a) UM has full right, title, and interest in and to the Patent Rights identified in Exhibit A-1 (subject to any rights of the United States under grants to UM and pursuant to 35 U.S.C. Section 201 et seq. and all implementing regulations), saving only the invention listed in Patent Rights which is jointly owned by UM and ISS; (b) the Patent Rights identified in Exhibit A-1 are not the subject matter of any currently pending claims, actions or litigation involving UM, and UM has not been informed of any related matters or litigation contemplated either by UM or any Third Party; and (c) UM is unaware that any person disputes inventorship or ownership of Patent Rights as described in this Agreement. [***]. UM warrants that the officer of UM executing this Agreement is authorized to do so on behalf of UM. UM EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, AND PATENT VALIDITY, WITH RESPECT TO PATENT RIGHTS.

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15.02 Company hereby represents and warrants to UM that: (a) Company has full legal right, power and authority to execute, deliver and perform its obligations under this Agreement; (b) the execution, delivery and performance by Company of this Agreement do not contravene or constitute a default under any provision of applicable law or of any agreement, judgment, injunction, order, decree, or other instrument binding upon Company; and (c) the officer of the Company executing this Agreement has been authorized by the Company's board of directors or governing body to execute this Agreement as the act of the Company.

ARTICLE 16. CLAIMS, INDEMNIFICATION AND INSURANCE

16.01 UM and its officers and employees acting within the scope of their employment by UM are subject to the Maryland Tort Claims Act ("the Act"), Title 12, Subtitle 1, State Government Article, Annotated Code of Maryland, which permits claims in tort against the State of Maryland under certain circumstances and subject to limits provided by law. In order to file a claim under the Act, a claimant must submit a written claim to the Treasurer of the State of Maryland or a designee of that office within one year after the injury to the person or property that is the basis of the claim.

16.02 Company warrants and represents that it maintains comprehensive liability insurance coverage for itself, its officers, employees and agents, in the minimum amounts of $[***] per claim and $[***] aggregate, applicable to bodily injury and property damage. Prior to the initiation of any human trials in any geographical location with any products, processes, or protocols developed either by Company, its Affiliates, or Sublicensees or their officers, servants, or agents, or by Third Parties acting on behalf of or under authorization from Company, its Affiliates or Sublicensees, using licensed Patent Rights, the Company will establish and maintain Product & Clinical Trials Liability insurance coverage in the amount of $[***] per claim and $[***] aggregate. Company warrants that its liability insurance will cover contractually assumed obligation for product liability claims referred to in Section 16.03, when/if human clinical trials are commenced. UM acknowledges that Company's liability insurance will not cover indemnity claims related to patent infringement referred to in Section 16.03. A certificate evidencing the required insurance coverage will be delivered to UM: (i) at or before execution of this Agreement; (ii) each time there is a change in Company's insurance coverage; and (iii) each time Company's insurance coverage is renewed. Company agrees to require its insurance carrier(s) to notify UM within 15 days prior to cancellation of Company's insurance coverage, except in the case of cancellation for nonpayment of premium, where 10 days advance notice will be provided. If Company does not secure liability insurance written on an occurrence basis, but instead secures liability insurance written on a claims-made basis, Company warrants that it will purchase extending reported coverage or otherwise provide insurance satisfying its obligations hereunder for a period of not less than [***] years following termination of this Agreement.

16.03 (a) Company will defend, indemnify, and hold harmless UM, UM Personnel, UM Affiliates, the University System of Maryland, the State of Maryland, and their regents, officers, employees, students, and agents (each individually a "UM Party" and all, collectively "UM Parties"), and ISS, against any and all claims, costs or liabilities, including attorney's fees and court costs at trial and appellate levels, for any loss, damage, personal injury, or loss of life:

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1. caused by the actions of Company, its Affiliates, or Sublicensees, or their officers, servants, or agents, or Third Parties acting on behalf of or under authorization from Company, its Affiliates or Sublicensees, in the performance of this Agreement;

2. arising out of use of licensed Patent Rights by Company, its Affiliates, or Sublicensees or their officers, servants, or agents, or by any Third Party acting on behalf of or under authorization from Company, its Affiliates, or Sublicensees; or

3. arising out of use by a Party of products, processes, or protocols developed either by Company, its Affiliates, or Sublicensees or their officers, servants, or agents, or by Third Parties acting on behalf of or under authorization from Company, its Affiliates or Sublicensees, using licensed Patent Rights, provided such use was consistent with any instructions, protocols or supervision provided by Company.

(b) Company's agreement to defend, indemnify and hold harmless a UM Party or ISS is conditioned upon:

1. UM or ISS, as the case may be, promptly notifying Company in writing after it receives notice of a claim, and
2. the UM Party seeking indemnification, or ISS, fully cooperating with Company in the defense of the claim.

(c) Company's agreement to defend, indemnify and hold harmless a UM Party or ISS will not apply to any claim, cost, or liability attributable to the negligent act or willful misconduct of the UM Party, ISS, or a Third Party acting outside the direction or control of Company.

16.04 UM and Company further agree that nothing in this Agreement will be interpreted as:

(a) a denial to either party of any remedy or defense available to it under the laws of the State of Maryland;

(b) the consent of the State of Maryland or its agents and agencies to be sued; or

(c) a waiver of sovereign immunity or any other governmental immunity of the State of Maryland and UM beyond the extent of any waiver provided by law.

ARTICLE 17. ADVERTISING AND PUBLICITY

17.01 Neither party will use the name of the other or any of its employees or personnel, or any adaptation thereof, in any advertising, promotional, or sales literature without prior written consent obtained from the other party. Company may not use the name of ISS in conjunction with the invention owned by ISS and licensed hereunder without first securing the consent of ISS. Either party may publicize the fact that the parties have made this Agreement.

ARTICLE 18. DISPUTE RESOLUTION

If a dispute between the parties related to this Agreement arises, either party, by notice to the other party, may have the dispute referred to the parties' respective officers designated below, or their successors, for attempted resolution by good faith negotiations within 30 days after the notice is received. The designated officers are as follows:

For Company: Chief Executive Officer
For UM: Vice President, Research and Development

In the event the designated officers are not able to resolve the dispute within this 30 day period, or any agreed extension, they will confer in good faith with respect to the possibility of resolving the matter through mediation with a mutually acceptable Third Party or a national mediation organization. The parties agree that they will participate in any mediation sessions in good faith in an effort to resolve the dispute in an infoitnal and inexpensive manner. All expenses of the mediator will be shared equally by the parties. Any applicable statute of limitations will be tolled during the pendency of a mediation initiated under this Agreement. Evidence of anything said or any admission made in the course of any mediation will not be admissible in evidence in any civil action between the parties. In addition, no document prepared for the purpose of, or in the course of, or pursuant to, the mediation, or copy thereof, will be admissible in evidence in any civil action between the parties. However, the admissibility of evidence will not be limited if all parties who participated in the mediation consent to disclosure of the evidence.

ARTICLE 19. MISCELLANEOUS

19.01 No license or right is granted by implication or otherwise with respect to any patent application or patent owned by either party, unless specifically set forth in this Agreement.

19.02 (a) Company will not knowingly employ or compensate, directly or indirectly, any person working in the Licensed Field, or involved in negotiating this Agreement on behalf of UM, while the person is employed by UM or for [***] thereafter, unless UM provides Company with prior written consent of the UM President to the employment or compensation by Company, which shall not be unreasonably withheld. "Compensation" includes but is not limited to: stock option or stock purchase agreements, consulting agreements, any other form of agreement executed between a UM employee and Company, and cash payments. "Employment" includes both uncompensated and compensated service to Company. The Maryland Public Ethics Law, Title 15, State Government Article, Annotated Code of Maryland, may apply to a decision by the UM President in regard to such matter.

(b) [***].

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

(c) Company and one of the Licensor Inventors, [***], are considering business relationships between them which may involve [***] being an officer, employee, or consultant of Company. As a consequence of the business relationship created by this Agreement between Company and [***]'s employer, UM, and as a consequence of the fact that [***] is an employee of the State of Maryland by virtue of his UM employment, [***]'s relationships with Company during the term of this Agreement would cause him to be in violation of the State Public Ethics Law (Title 15, Subtitle 5, State Government Article, Annotated Code of Maryland), unless an exemption is granted to him by UM. The same situation would pertain to any other UM Personnel who have responsibilities relating to Patent Rights or this Agreement who may consider business relationships with Company. Company agrees that it will not enter into any paid or unpaid employment or other business relationship with [***] or other UM Personnel without verifying with the UM Conflict of Interest Officer that to do so will not cause the UM Personnel in question to be in violation of the State Public Ethics Law.

19.03 If Company conducts clinical trials of a Licensed Product, it will give full consideration to using UM or the University of Maryland Medical System Corporation as a site for clinical trials, subject to agreement on terms and conditions, including compensation, negotiated in good faith.

19.04 Neither party is liable for failure or delay in performing any of its obligations under this Agreement if the failure or delay is required in order to comply with any governmental regulation, request or order, or necessitated by other circumstances beyond the reasonable control of the party so failing or delaying, including but not limited to Acts of God, war (declared or undeclared), insurrection, fire, flood, accident, labor strikes, work stoppage or slowdown (whether or not such labor event is within the reasonable control of the parties), or inability to obtain raw materials, supplies, power or equipment necessary to enable a party to perform its obligations. Each party will: (a) promptly notify the other party in writing of an event of force majeure, the expected duration of the event and its anticipated effect on the ability of the party to perform its obligations; and (b) make reasonable efforts to remedy the event of force majeure.

19.05 All notices, consents and other communications required or allowed under this Agreement must be in writing and are effective upon receipt: (a) when delivered by hand; or (b) when received by the addressee after being mailed by registered or certified mail (air mail if mailed overseas), return receipt requested; or (c) when received by the addressee, by delivery service (return receipt requested), in each case addressed to the party at its address set forth below (or to another address that a party may later designate by notice to the other party):

If to UM: Director, Technology Commercialization
Office of Research and Development
University of Maryland, Baltimore
515 West Lombard Street, Fourth Floor
Baltimore, Maryland 21201-1602

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

Copy to: University Counsel
University of Maryland, Baltimore
520 West Lombard Street
East Hall, Second Floor
Baltimore, Maryland 21201-1627

If to Company: Chief Executive Officer
Alba Therapeutics Corporation
2400 Boston St., Suite 310
Baltimore, MD 21224

Copy to : General Counsel
Alba Therapeutics Corporation
2400 Boston Street
Suite 302
Baltimore, MD 21224

19.06 This Agreement, including Exhibits, may not be amended, nor may any right or remedy of either party be waived, unless the amendment or waiver is in writing and signed by a duly authorized representative of each party.

19.07 A failure or delay by a party in exercising any of its rights or remedies under this Agreement does not constitute a waiver of the rights or remedies, nor does any single or partial exercise of any right or remedy preclude any other or further exercise thereof or the exercise of any other right or remedy. The rights and remedies of the parties provided in this Agreement are cumulative and not exclusive of any rights or remedies provided by law.

19.08 UM and Company are not (and nothing in this Agreement may be construed to constitute them as) partners, joint venturers, agents, representatives or employees of the other, nor is there any status or relationship between them other than that of independent contractors. Neither party has any responsibility nor liability for the actions of the other party except as specifically provided in this Agreement. Neither party has any right or authority to bind or obligate the other party in any manner or make any representation or warranty on behalf of the other party.

19.09 Unless otherwise provided, all costs and expenses incurred in connection with this Agreement will be paid by the party which incurs the cost or expense, and the other party has no liability for such cost or expense.

19.10 This Agreement is not intended to create, and does not create, enforceable legal rights as a third party beneficiary or through any other legal theory on the part of any University Personnel or any other person except as otherwise provided by Section 16.03.

19.11 This Agreement is signed in duplicate originals. The headings used in this Agreement are for convenience of reference only and do not affect the meaning or construction of this Agreement.

[remainder of page intentionally blank]
[signatures on following page]

The parties have caused this Agreement to be executed by their duly authorized representatives on the dates indicated below.

UNIVERSITY OF MARYLAND,
BALTIMORE

BY: /s/ David J. Ramsay
WITNESS: /s/ Dorothy C. Trueheart
David J. Ramsay, D.M., D.Phil.
President

Date: 10/5/2005
Date: 10/5/2005

ALBA THERAPEUTICS CORPORATION

BY: /s/ Blake M. Paterson
WITNESS: /s/ [illegible]
Blake M. Paterson, MD
Corporate Secretary
President

Date: 14 Oct 2005
Date: 10/14/05

EXHIBIT A-1: PATENT RIGHTS

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

EXHIBIT A-2: ROYALTY RATES

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

EXHIBIT B: INVENTION REPORTS

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

EXHIBIT C: SAMPLE MATERIAL TRANSFER AGREEMENT

See attached file MTA070704

EXHIBIT C

**MATERIAL TRANSFER AGREEMENT FOR ZOT AND ZONULIN,
SUBJECT TO LICENSE AGREEMENT WITH
ALBA THERAPEUTICS CORPORATION**

This MATERIAL TRANSFER AGREEMENT (this "Agreement") dated as of _____, _____ (the "Effective Date"), is entered into by and between the University of Maryland, Baltimore, a constituent institution of the University System of Maryland, which is a public corporation and an instrumentality of the State of Maryland, located at 520 West Lombard Street, Baltimore Maryland 21201 ("PROVIDER"), and _____, a _____ institution located at _____, ("RECIPIENT"), on behalf of ("RECIPIENT SCIENTIST").

The parties agree as follows:

1. The terms "PROVIDER", "RECIPIENT", and "RECIPIENT SCIENTIST" have the meanings indicated above. Other terms used in this Agreement are defined as follows:

1.1. ***AGONISTS/ANTAGONISTS***: Agonists or antagonists to a receptor protein created through the use of the MATERIAL by RECIPIENT that are not PROGENY, MODIFICATIONS or UNMODIFIED DERIVATIVES.

1.2. ***COMMERCIAL PURPOSES*:** The sale, lease, license, or other transfer of the MATERIAL, MODIFICATIONS, or AGONISTS/ANTAGONISTS to a for-profit organization. COMMERCIAL PURPOSES includes uses of the MATERIAL, MODIFICATIONS or AGONISTS/ANTAGONISTS by any organization, including RECIPIENT, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL, MODIFICATIONS or AGONISTS/ANTAGONISTS to a for-profit organization. However, industrially sponsored academic research will not be considered a use of the MATERIAL, MODIFICATIONS or AGONISTS/ANTAGONISTS for COMMERCIAL PURPOSES per se, unless any of the above conditions of this definition are met.

1.3. ***LICENSEE*:** Alba Therapeutics Corporation, which has licensed from PROVIDER certain specific and exclusive rights to use the MATERIAL for COMMERCIAL PURPOSES.

1.4. ***MATERIAL*:** PROVIDER's ORIGINAL MATERIAL, PROGENY, and UNMODIFIED DERIVATIVES and its associated confidential and proprietary data and information.

1.5. ***MODIFICATIONS*:** Substances created by RECIPIENT which contain or incorporate the MATERIAL.

1.6. ***NONPROFIT ORGANIZATION(S)*:** A university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute. As used herein, the term also includes government agencies.

1.7. ***ORIGINAL MATERIAL*:** Zot, Zonulin: "Zonula Occludens Toxin" otherwise known as Zot, Zonulin, covered under various US & foreign patents.

1.8. ***PROGENY*:** Unmodified descendant from the MATERIAL, such as virus from virus, cell from cell, or organism from organism.

1.9. ***PROVIDER SCIENTIST*:** [***], an employee of PROVIDER, or scientists working under his direct supervision.

1.10. ***UNMODIFIED DERIVATIVES*:** Substances created by RECIPIENT which constitute an unmodified or modified functional sub-unit or product expressed by the ORIGINAL MATERIAL. Some examples include: subclones of unmodified or modified cell lines, purified or fractionated sub-sets of the ORIGINAL MATERIAL, proteins expressed by DNA/RNA supplied by PROVIDER, or "-monoclonal antibodies secreted by a hybridomas cell line.

2. PROVIDER shall provide RECIPIENT with the MATERIAL on the terms and conditions of this Agreement.

3. PROVIDER retains all right and title in the MATERIAL and MODIFICATIONS. RECIPIENT shall use the MATERIAL and MODIFICATIONS solely for the following, non-commercial, research purposes: _____.

RECIPIENT UNDERSTANDS THAT THE MATERIAL IS PROVIDED SOLELY FOR NON-HUMAN RESEARCH PURPOSES, HAS NOT BEEN APPROVED FOR USE WITH HUMAN SUBJECTS INCLUDING FOR DIAGNOSTIC PURPOSES, AND CANNOT AND WILL NOT BE ADMINISTERED TO HUMAN SUBJECTS.

4. MATERIAL is to be used only at the RECIPIENT organization and only in the RECIPIENT SCIENTIST's laboratory under the direction of the RECIPIENT SCIENTIST or others working under his/her direct supervision. MATERIAL will not be transferred to anyone else within the RECIPIENT organization without the prior written consent of the PROVIDER. RECIPIENT shall limit transfer and disclosure of the MATERIAL only as reasonably necessary for completion of the research described above, which may include, without limitation of the forgoing, transfer and disclosure to RECIPIENT's directors, officers, employees, consultants and legal advisors.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

5. RECIPIENT and RECIPIENT SCIENTIST agree to refer to PROVIDER any request for MATERIAL from any person or entity other than those persons who are working under the RECIPIENT SCIENTIST's direct supervision and persons described in the last sentence of paragraph 4 above.

6. RECIPIENT agrees that MATERIAL, MODIFICATIONS, and AGONISTS/ANTAGONISTS will be transferred to anyone else other than RECIPIENT'S SCIENTIST and permitted persons within RECIPIENT organization only under a material transfer agreement between PROVIDER and RECIPIENT organization with terms at least as restrictive as the terms of this Agreement.

7. RECIPIENT agrees that MATERIAL, MODIFICATIONS, and AGONISTS/ANTAGONISTS are subject to certain rights of LICENSEE.

8. To the extent supplies of MATERIAL are available, PROVIDER or PROVIDER SCIENTIST will make MATERIAL available, under a separate implementing letter to this Agreement or other agreement having terms consistent with the terms of this Agreement, only to other scientists at NONPROFIT ORGANIZATION(S) who wish to replicate RECIPIENT SCIENTIST's research; provided that such other scientists reimburse PROVIDER for any costs relating to the preparation and distribution of MATERIAL.

9. (a) RECIPIENT will have the right, without restriction, to distribute substances created by RECIPIENT through the use of MATERIAL only if such substances are not PROGENY, UNMODIFIED DERIVATIVES, MODIFICATIONS, or AGONISTS/ANTAGONISTS.

   (b) Upon notice to PROVIDER and under the Uniform Biological Material Transfer Agreement published in the Federal Register on March 8, 1995 (or an agreement at least as protective of PROVIDER's and LICENSEE's rights), RECIPIENT may distribute MODIFICATIONS and AGONISTS/ANTAGONISTS to non-profit or governmental organizations for non-commercial research purposes only.

10. RECIPIENT acknowledges that MATERIAL is the subject of patents and patent applications, and significant rights granted to LICENSEE. Except as expressly provided in this Agreement, no express or implied licenses or other rights are provided to RECIPIENT under any patents, patent applications, trade secrets or other intellectual property rights of PROVIDER, including with respect to PROGENY, MODIFICATIONS, UNMODIFIED DERIVATIVES or AGONISTS/ANTAGONISTS, or other modified forms of the MATERIAL. In particular, but without limiting the foregoing, no express or implied licenses or other rights are provided to use MATERIAL, MODIFICATIONS, AGONISTS/ANTAGONISTS or any related patents of PROVIDER, including patents covering the composition of matter, methods of manufacture or use of any of the foregoing, for any COMMERCIAL PURPOSES. This agreement shall not be construed to grant any license or other grants to RECIPIENT in the MATERIAL or MODIFICATIONS or AGONISTS/ANTAGONISTS, or under any patent rights or other intellectual property rights of PROVIDER or LICENSEE.

11. RECIPIENT is free to file patent application(s) claiming inventions made by RECIPIENT through the use of provided MATERIAL but agrees to notify PROVIDER thirty (30) days prior to filing a patent application claiming MODIFICATIONS, or AGONISTS/ANTAGONISTS or method(s) of manufacture or use(s) of provided MATERIAL.

12. This Agreement will terminate upon the earliest of the following: (1) one (1) year from the Effective Date; (2) one (1) year from the actual receipt of the MATERIAL; (3) when MATERIAL becomes generally available from third parties, such as through reagent banks or from public repositories; (4) upon completion of RECIPIENT's current research with MATERIAL; or (5) upon thirty (30) days written notice of termination by either party. Upon the request of PROVIDER, RECIPIENT shall either promptly destroy or return to PROVIDER all remaining MATERIAL.

13. Termination of this Agreement under Section 12 above will have the following consequences:
(a) if termination should occur under Section 12(3) above, RECIPIENT will be bound to PROVIDER by the least restrictive terms applicable to MATERIAL obtained from the-then-available sources; and
(b) if termination should occur under Section 12(4) above, RECIPIENT will discontinue its use of MATERIAL and will, upon direction of PROVIDER, return or destroy any remaining MATERIAL. RECIPIENT, at is discretion, will also either destroy MODIFICATIONS or remain bound by the terms of this Agreement as they apply to MODIFICATIONS; and
(c) if PROVIDER terminates this Agreement under Section 12(5) above, other than for breach of this Agreement or with cause such as an imminent health risk or patent infringement by RECIPIENT and/or RECIPIENT SCIENTIST, PROVIDER may defer the effective date of termination for a period of up to one (1) year, upon' request from RECIPIENT, ("Deferred Date of Termination") to provide RECIPIENT an opportunity to complete research in progress, e.g., on-going experiments. Upon the effective date of termination, or if granted by PROVIDER, the Deferred Date of Termination, RECIPIENT will discontinue its use of MATERIAL and will, upon direction of PROVIDER, return or destroy any remaining MATERIAL. RECIPIENT, at its discretion, also will destroy MODIFICATIONS and AGONISTS/ANTAGONISTS or remain bound by the terms of this Agreement as they apply to MODIFICATIONS and AGONISTS/ANTAGONISTS.

14. RECIPIENT hereby acknowledges that the MATERIAL is experimental in nature, may have hazardous properties, and is provided "AS IS." PROVIDER MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO THE MATERIAL OR THE USE THEREOF. PROVIDER DISCLAIMS ALL LMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.

15. RECIPIENT shall comply in all material respects with all laws and governmental rules, regulations and guidelines which are applicable to the MATERIAL or the use thereof, including biosafety procedures, and with any safety precautions accompanying the MATERIALS.

16. RECIPIENT assumes all liability for damages that may arise from its use, storage or disposal of the MATERIAL. PROVIDER will not be liable to RECIPIENT for any loss, claim or demand made by RECIPIENT, or made against RECIPIENT by any other party, due to or arising from the use of the MATERIAL by RECIPIENT, except to the extent provided by Maryland law with respect to a tort claim asserted by RECIPIENT against PROVIDER.

17. This Agreement represents the entire agreement between the parties regarding the subject matter hereof and shall supersede all previous communications, representations, understandings and agreements, whether oral or written, by or between the parties with respect to the subject matter hereof.

18. No change, modification, extension, termination or waiver of this Agreement, or any of the provisions herein contained, shall be valid unless made in writing and signed by duly authorized representatives of the parties.

19. All necessary and relevant Paragraphs will survive termination of this Agreement for any reason whatsoever where it is clear from the content of those Sections that they are intended to survive, including without limitation, Sections, 1, 6, 13, 14, 15 and 21.

20. MATERIAL will be provided following payment to PROVIDER of a processing fee of _____.

21. This Agreement may not be interpreted to prevent or to delay publication of research findings resulting from the use. of MATERIAL, MODIFICATIONS or AGONISTS/ANTAGONISTS. RECIPIENT SCIENTIST agrees to provide appropriate acknowledgment of the source of MATERIAL in all publications.

22. RECIPIENT will provide to PROVIDER written progress reports of all data generated from the research in which MATERIAL is used, and a final written report regarding the research results within sixty days (60) of completion of RECIPIENT’s research with the MATERIAL.

IN WITNESS WHEREOF, the parties have entered into this Agreement as of the Effective Date.

UNIVERSITY OF MARYLAND, BALTIMORE

By: _____

Title: _____

[RECIPIENT]

By: _____

Title: _____

EXHIBIT A

MATERIALS

[TO BE COMPLETED]

EXHIBIT D: PATENT EXPENSES INCURRED PRIOR TO THE EFFECTIVE DATE

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

EXHIBIT E

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

FIRST AMENDMENT

to

RESTATED

MASTER LICENSE AGREEMENT

effective July 1, 2005
between
UNIVERSITY OF MARYLAND, BALTIMORE
and
ALBA THERAPEUTICS CORPORATION

This First Amendment ("Amendment") to Restated Master License Agreement ("Agreement") effective July 1, 2005, is made by and between the University of Maryland, Baltimore ("UM"), a constituent institution of the University System of Maryland, a public corporation and an instrumentality of the State of Maryland, having an address at 520 West Lombard Street, East Hall, Room 200, Baltimore, Maryland 21201, and Alba Therapeutics Corporation, a corporation of Delaware, with its principal place of business at 2400 Boston St., Suite 310, Baltimore, MD 21224 ("Company").

For [***] and other valuable consideration, receipt of which is acknowledged, the parties agree as follows:

1. This Amendment is effective December 1, 2005.

2. Section 3.01 of the Agreement is deleted in its entirety and replaced with the following provision:

"3.01 Subject to rights of the United States under grants to UM and pursuant to 35 U.S.C. Section 201 et seq. and all implementing regulations, and subject to Section 3.02, UM grants to Company, and Company accepts, an exclusive worldwide license under Patent Rights to conduct research and development and to make, have made, use, lease, offer to sell, sell and import the Licensed Products within the Licensed Field as defined in Section 2.12 above, for the term of this Agreement. This license includes the right to grant sublicenses consistent with this Agreement."

3. Section 3.09(a) of the Agreement is deleted in its entirety and replaced with the following provision:

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

"3.09 (a) Subject to rights of other parties sponsoring research at UM, Company has an exclusive option to enter into an exclusive license agreement with UM for UM Rights in Improvements, within the Licensed Field, so long as (i) this Agreement is in effect, (ii) Company files, prosecutes, and maintains patent applications and issued patents for Patent Rights and UM Rights in Improvements and pays Patent Expenses for Patent Rights and UM Rights in Improvements to the extent required by this Agreement, and (iii) Company has not notified UM that Company declines to exercise its option. During the term of this option, UM Rights in Improvements will be subject to the same patent prosecution and maintenance terms and conditions applicable to Patent Rights under Article 7 of this Agreement."

4. Section 3.11(a) of the Agreement is deleted in its entirety and replaced with the following provision:

"3.11 (a) UM will report promptly to Company in writing each UM Improvement and each Joint Improvement disclosed to UM. Company will report promptly to UM in writing each UM Improvement and each Joint Improvement disclosed to Company. This reporting requirement is triggered by determination by the receiving party that a disclosed invention concerns a UM Improvement or Joint Improvement. A copy of a provisional patent application filed by UM for the UM Improvement or Joint Improvement will satisfy this reporting requirement. IF UM does not file a patent application, Company will do so upon UM's request. Promptly after filing of any patent application related to Patent Rights, UM Improvements or Joint Improvements, UM and Company will confer in good faith to determine inventorship of the intellectual property described in the patent application."

5. Article 4 of the Agreement is amended by the addition of the following Section 4.06:

4.06 Company will file, prosecute and maintain any patent applications and issued patents related to Patent Rights, UM Improvements and Joint Improvements pursuant to the terms and conditions of Section 7 of this Agreement.

6. Article 7 of the Agreement is deleted in its entirety and replaced with the following Article 7:

"ARTICLE 7. PATENT PROSECUTION AND PUBLICATIONS

7.01 (a) UM is responsible for filing and prosecuting patent applications for the Patent Rights and UM Improvements through November 30, 2005; Company is responsible for filing any patent applications for the Patent Rights and UM Improvements on and after December 1, 2005, subject to UM's continuing ability to file provisional applications on UM Improvements and to withdraw from Company the responsibility to file and prosecute applications relating to UM Improvements (see 7.01(g)). Company is responsible for filing and prosecuting any patent applications for Joint Improvements unless Company and UM agree in writing that UM will assume such responsibility for any or all of Joint Improvements. Company is responsible for the filing, prosecution, and maintenance of patent applications for Company Improvements.

(b) The scope of patent coverage within Patent Rights, UM Improvements, or Joint Improvements will not be significantly modified or limited, and the identification of inventors will not be modified, by the party responsible for filing patent applications without prior approval of the other party. If approval is requested by notice in writing, and is neither given nor denied in writing within 10 business days after the date notice is received, approval will be deemed given.

(c) UM will invoice Company for Patent Expenses incurred by UM. Company will pay the invoice in full to UM within 30 days after the date of UM's invoice. Company's failure to pay an invoice on time will result in interest charges in accordance with Section 5.10 as well as loss of input into patenting decisions until such time as Company pays all outstanding invoices for Patent Expenses and accrued interest. Additionally, Company's failure to pay an invoice and accrued interest within 90 days after date of invoice will result in termination of Company's option rights under Section 3.09. Fees incurred by Company for patent action are Company's responsibility.

(d) Further, with respect to Patent Rights and UM Improvements, and with respect to the filing and prosecution of foreign patent applications specified by Company or filed by Company in accordance with Section 7.04, Company will pre-pay or directly pay charges and fees, including attorneys' fees, or will reimburse UM for those charges and fees, at UM's option, if such charges and fees were incurred prior to December 1, 2005, result from instructions given by UM prior to December 1, 2005, or otherwise were incurred by UM as a result of agreement with Company or pursuant to the terms of this Agreement.

(e) Company will choose outside patent counsel subject to UM's approval, which approval must not be withheld or delayed unreasonably. If UM has not approved or disapproved patent counsel within 10 business days of notice of a request for approval, UM's approval shall be deemed given. Fees incurred by Company for patent action are Company's sole responsibility.

(f) If Company chooses not to file a patent application for a Patent Rights, a UM Improvement or a Joint Improvement, or chooses to abandon a patent application or an issued patent for any or all of Patent Rights, a UM Improvement or a Joint Improvement, it will give UM 30 days prior notice, and UM may file, prosecute or maintain the patent application or issued patent at its own expense if it chooses. Company will act in good faith to maintain and meet all deadlines occurring during the 30 day period. Company's license of the Patent Rights or UM's interest in the UM Improvement or Joint Improvement will terminate as of the date Company gives notice of its decision.

(g) If UM and Company do not agree on actions relating to scope of patent coverage for any of Patent Rights, UM Improvements or Joint Improvements, then UM may terminate immediately Company's right to prosecute the patent application(s) involved, and in such case UM may continue prosecution, using its own, independent counsel. Patent Expenses incurred under this paragraph for the patent application or issued patent involved shall be paid by Company unless Company notifies UM that Company chooses to terminate its license of the Patent Rights, UM Improvements or Joint Improvements involved.

(h) For purposes of this Agreement, all UM Personnel or Company Personnel who are considered inventors of an Improvement under United States patent law will be listed as inventors of that Improvement. Only inventorship under U.S. law will be considered in determining whether an Improvement is a Company Improvement, Joint Improvement or UM Improvement. The Parties recognize that the patent laws of countries where patent applications are filed may follow rules of inventorship that differ from U.S. patent law. If the parties do not agree as to inventorship, the matter will be submitted to patent counsel acceptable to both parties for binding resolution. The party prosecuting the application in question will designate counsel to advise the parties. The other party may reject this designation by notice given within 10 days after receipt of the proposal. This notice will include two proposed alternative counsel. The first party will choose one of the two, and the parties will use that counsel. Costs associated with evaluation of inventorship will be divided equally between the parties.

7.02 (a) If Company does not license UM Improvements or UM's Interest in Joint Improvements, then Company will have no obligation under Section 7.01 to file or prosecute a patent application for the UM Improvements or Joint Improvements, or under Section 3.09(a) to pay Patent Expenses related to the UM Improvements or Joint Improvements incurred by UM for patent filing and prosecution activities occurring more than 60 days after Company's option is terminated or expires as provided in Section 3.09. UM will act in good faith to minimize the Patent Expenses incurred between receipt of notice and the end of the 60 day period. If Company is responsible for prosecution or maintenance of the patent applications for UM Improvements or Joint Improvements involved, then Company will act in good faith to maintain the patent applications and meet all deadlines occurring during the 60-day period.

(b) If this Agreement is terminated for any reason other than expiration in accordance with Section 11.01, Company will have no obligation to pay Patent Expenses related to Patent Rights or UM Improvements incurred by UM for patent filing and prosecution activities occurring more than 60 days after termination, and no obligation to pursue patent applications related to Patent Rights or UM Improvements and pay related Patent Expenses for more than 60 days after termination. UM will act in good faith to minimize the Patent Expenses it incurs between receipt of notice of termination and the end of the 60 day period.

7.03 Company and UM will cooperate to limit the Patent Expenses while making reasonable efforts to have the Patent Rights cover all items of commercial interest and importance. Company and UM will cooperate to define the scope and content of U.S. and foreign patent applications to be filed under Patent Rights, UM Improvements and Joint Improvements. Company will give UM reasonable opportunity to advise Company and patent counsel with respect to patent applications prosecuted by Company pursuant to this Agreement. The parties will cooperate with each other in the prosecution, filing, and maintenance of their respective patent applications covering Patent Rights. Company will advise UM promptly as to all material developments with respect to the applications. Copies of all papers received and filed by Company in connection with prosecution of applications will be provided promptly to UM to enable it to advise Company thereon.

7.04 (a) UM has disclosed to Company or Company has disclosed to UM the patent applications and patents in effect for the Patent Rights listed in Exhibit A-1. With respect to patent application Serial Numbers [***], or further patent applications related to invention reports listed in Exhibit B, or UM Improvements, Company will file patent applications in [***], and additional countries chosen by Company. If Company gives at least 60 days prior written notice to UM, Company may elect to discontinue patent prosecution and support for Patent Expenses in any country other than [***]. Company will be responsible for Patent Expenses incurred in that 60 day period with respect to the country or countries where Company is ceasing support. From and after UM's receipt of Company's notice, Company's exclusive rights in Patent Rights and UM Rights in Improvements will become non-exclusive with respect to the country or countries where Company is ceasing support, and Company will execute such documents as reasonably may be requested by UM to confirm conversion of Company's rights.

(b) UM may elect to file and prosecute patent applications, solely at its own expense, in foreign countries not listed in Section 7.04(a) or not chosen by Company. If UM so elects, Company will have no right to approve UM's patent counsel, no license rights with respect to Patent Rights and UM Improvements in those countries, and no option rights with respect thereto in those countries, unless otherwise agreed to by the parties in writing.

7.05 In order to preserve the ability to secure patents or equivalent foreign protection for Patent Rights, UM Improvements and Joint Improvements, UM will request that UM Personnel not disseminate or publish any results or otherwise publicly disclose the results of research performed by UM Personnel relating to the Patent Rights within the Licensed Field and subject to the license(s) granted to Company under this Agreement unless any materials containing those results are first submitted to UM and, by UM, to Company, for review, comment, and consideration of appropriate patent action. UM will inform UM Personnel working with Patent Rights that they are required to submit materials relating to a planned written publication or other public disclosure to UM for review at least 90 days prior to the date of the planned submission for written publication or other disclosure. UM will promptly advise Company of any proposed publications or public disclosures reported to UM and will furnish Company a copy of the proposed publication or public disclosure as soon as submitted to UM. Company will advise UM within 30 days after Company's receipt of the materials whether patent applications will be filed by Company in connection with obtaining or maintaining Patent Rights related to the materials submitted by UM. UM will advise UM Personnel that they must delay written publication or public disclosure up to a maximum of 60 days after the date Company receives the materials to enable Company to file, at Company's expense, any patent applications Company chooses to file."

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

7. The parties have caused this Amendment to be executed by their duly authorized officers on the dates indicated below.

UNIVERSITY OF MARYLAND,
BALTIMORE

BY: /s/ David J. Ramsay
David J. Ramsay, D.M., D.Phil.
President

WITNESS /s/ Dorothy C. Trueheart

Date: 12/9/05

Date: 12/9/05

ALBA THERAPEUTICS CORPORATION

BY: /s/ Blake M. Paterson
Blake M. Paterson, MD
President and CEO

WITNESS /s/ [illegible]
Corporate Secretary

Date: 12/1/2005

Date: 12/1/05

SECOND AMENDMENT
to
RESTATED
MASTER LICENSE AGREEMENT

effective July 1, 2005
between
UNIVERSITY OF MARYLAND, BALTIMORE
and
ALBA THERAPEUTICS CORPORATION

This Second Amendment ("Second Amendment") to the Restated Master License Agreement effective July 1, 2005, is made by and between the University of Maryland, Baltimore, a constituent institution of the University System of Maryland, a public corporation and an instrumentality of the State of Maryland, having an address at 520 West Lombard Street, East Hall, Room 200, Baltimore, Maryland 21201 ("UM"), and Alba Therapeutics Corporation, a Delaware corporation, with its principal place of business at 800 West Baltimore St., Suite 400, Baltimore, MD 21201 ("Company").

RECITALS

A. UM and Company are parties to the Agreement, as amended by the First Amendment to Restated Master License Agreement effective December 1, 2005. The Agreement, as amended by the First Amendment, is referred to as "the Agreement" in these Recitals.

B. UM has disclosed to Company [***] inventions that are "UM Improvements" under the Agreement, and Company has exercised its option, under the Agreement, to license the inventions. The [***] UM Improvements are: [***].

C. The Parties have agreed to amend the Agreement to include the UM Improvements identified in the preceding paragraph as licensed Patent Rights, and to state the consideration due UM for this change in the Agreement.

D. The Parties have recognized that it is necessary and appropriate to confirm license to Company, under the Agreement, of UM's joint undivided interest in U.S. Patent Appln. [***].

E. UM has disclosed to Company certain Invention Reports that are not reflected in Exhibit B to the Agreement, and the parties have agreed to add those Invention Reports to Exhibit B, acknowledging that the patent applications and patents based on those Invention Reports will be Patent Rights as defined in the Agreement.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

NOW, THEREFORE, in consideration of the mutual promises set forth in the Agreement, and in this Second Amendment, and for other good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

Amendments

1. This Second Amendment is effective February 15, 2007. On and after that date, the term "Agreement" as used in the Restated Master License Agreement or either amendment of it shall mean the Restated Master Licensed Agreement as amended by both the First Amendment and this Second Amendment.

2. Exhibit A-1 is amended by addition of the following descriptions of Patent Rights:

[***]

3. Exhibit B of the Agreement is deleted in its entirety and replaced with the attached list of invention reports captioned "Exhibit B — Amended 2/15/2007".

4. Section 4.01(d)5. is deleted in its entirety and replaced with the following Section 4.01(d)5.:

[***]

5. Section 5.01(a) is amended by the addition of the following language as a new paragraph 4:

[***]

6. Section 5.12 is amended by the addition of the following language as a new subsection 5.12(g):

"(g) For and in consideration of (i) the grant of license to the UM Improvements identified in paragraph 2 of the Second Amendment of this Agreement, and added to Exhibit A-1, and (ii) the commitment of UMB to license under the Agreement, for no additional consideration, Patent Rights based upon UM Improvements identified in paragraph 3 of the Second Amendment, Company will pay to UM [***]. This payment is due no later that [***]."

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

7. In Section 19.05, the notice addresses are deleted in their entirety and replaced with the following addresses:

If to UM:

Address for postal mail ONLY:
Director, Technology Commercialization
Office of Research and Development
University of Maryland, Baltimore
660 West Redwood Street, Room 021
Baltimore, Maryland 21201-1541

Address for other forms of communication permitted by this Agreement:
Director, Technology Commercialization
Office of Research and Development
University of Maryland, Baltimore
110 South Paca Street
Fourth Floor
Baltimore, Mary land 21201

Copy to:
University Counsel
University of Maryland Baltimore
520 West Lombard Street
East Hall, Suite 200
Baltimore, Maryland 21201-1627

If to Company:
Chief Executive Officer
Alba Therapeutics Corporation
800 West Baltimore Street
Suite 400
Baltimore, MD 21201

Copy to:
General Counsel
Alba Therapeutics Corporation
800 West Baltimore Street
Suite 400
Baltimore, MD 21201

IN WITNESS WHEREOF, the Parties hereto have caused this Second Amendment to be executed by their duly authorized officers.

UNIVERSITY OF MARYLAND,
BALTIMORE

BY: /s/ David J. Ramsay
David J. Ramsay, D.M., D.Phil.
President

Date: 3/14/07

WITNESS /s/ Dorothy C. Trueheart

Date: 3/14/07

ALBA THERAPEUTICS CORPORATION

BY: /s/ Blake M. Paterson
Blake M. Paterson, MD
President and CEO

Date: 13 March 2007

WITNESS/s/ Teresa Wenhauer

Date: 3/13/07

EXHIBIT B AMENDED 2-15-2007

INVENTION REPORTS

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

THIRD AMENDMENT
to
RESTATED
MASTER LICENSE AGREEMENT

effective July 1, 2005
between
UNIVERSITY OF MARYLAND, BALTIMORE
and
ALBA THERAPEUTICS CORPORATION

This Third Amendment ("**Third Amendment**") to the Restated Master License Agreement effective July 1, 2005, as amended, is made by and between the UNIVERSITY OF MARYLAND, BALTIMORE, a constituent institution of the University System of Maryland, a public corporation and an instrumentality of the State of Maryland ("**UM**"), and ALBA THERAPEUTICS CORPORATION, a Delaware corporation ("**Company**").

RECITALS

A. UM and Company are parties to the Restated Master License Agreement effective July 1, 2005, as amended by the First Amendment effective December 1, 2005, and by the Second Amendment effective February 15, 2007. The Restated Master License Agreement, as amended, is referred herein to as the "**Agreement**." Company and UM have agreed to amend the Agreement as set forth herein.

B. An invention has been made jointly by Company and UMB known as [***]. The parties agree that the invention constitutes a "Joint Improvement" under the Agreement. Company has exercised its option under the Agreement to license UM's interest in the invention, on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual promises set forth in the Agreement, and in this Third Amendment, and for other good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

Amendments

1. The effective date of this Third Amendment shall be the date of the last signature on the signature page. On and after that date, the term "Agreement" as used in the Restated Master License Agreement or either amendment of it shall mean the Restated Master Licensed Agreement as amended by the First Amendment, the Second Amendment, and this Third Amendment.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

2. Exhibit A-1 is amended by addition of the following description of Patent Rights:

[***]

3. Section 4.01(d)(3) is deleted in its entirety and replaced with the following:

3. Left-intentionally blank.

4. Section 4.01(d)(6) is deleted in its entirety and replaced with the following:

[***]

5. Section 5.12 is amended by addition of the following language as a new subsection 5.12(h):
"(h) For and in consideration of the grant of an exclusive license to UM's rights in the Joint Improvement identified in paragraph 2 of this Third Amendment, and added to Exhibit A-1, Company will pay to UM [***]. This payment is due [***]."

6. Article 5 of the Agreement is further amended by the addition of the following Section 5.13:

5.13 In consideration of UM's agreement to amend the Agreement as set forth in this Third Amendment, Company agrees to pay the following:

(a) [***]

(b) [***]

7. Section 11.02 is deleted in its entirety and replaced with the following:

11.02 (a) Should Company fail to pay UM any sum due and payable under this Agreement, UM may terminate this Agreement on 90 days written notice, unless Company pays UM within the 90 day period all delinquent sums together with interest due and unpaid. Upon expiration of the 90 day period, if Company has not paid all sums and interest due and payable, the rights, privileges, and licenses granted under this Agreement terminate.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

(b) Notwithstanding the foregoing, if the delinquent sum and/or interest is only with respect to the [***] fee payable under Section 5.13(b), then UM may only terminate the rights, privileges, and licenses granted under this Agreement with respect to [***], and the other rights, privileges, and licenses granted under this Agreement of the Agreement shall remain in full force and effect.

8. In Section 19.05, the notice addresses are deleted in their entirety and replaced with the following addresses:

If to UM: Assistant Vice President, CVIP
Office of Research and Development
University of Maryland, Baltimore
620 West Lexington Street, 4th Floor
Baltimore, Maryland 21201

Copy to: University Counsel
University of Maryland Baltimore
520 West Lombard Street
East Hall, Suite 200
Baltimore, Maryland 21201-1627

If to Company: Chief Executive Officer

Alba Therapeutics Corporation
800 West Baltimore Street, Suite 400
Baltimore, Maryland 21201

Copy to: General Counsel
Alba Therapeutics Corporation
800 West Baltimore Street, Suite 400
Baltimore, Maryland 21201

9. Except as specifically modified in this Third Amendment, all terms and conditions of the Agreement shall remain in full force and effect.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

IN WITNESS WHEREOF, the Parties hereto have caused this Third Amendment to be executed by their duly authorized officers.

WITNESS:

/s/ [illegible]

UNIVERSITY OF MARYLAND, BALTIMORE

By: /s/ David J. Ramsay (SEAL)
David J. Ramsay, D.M., D.Phil.
President

Date: December 2, 2008

ATTEST:

ALBA THERAPEUTICS CORPORATION

By: /s/ Bruce A. Peacock (SEAL)
Bruce A. Peacock
President and CEO

Date: December 1, 2008

EXHIBIT B

PATENT RIGHTS

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

Exhibit 10.2

LICENSE AGREEMENT

effective February 26, 2016

between

ALBA THERAPEUTICS CORPORATION

and

INNOVATE BIOPHARMACEUTICALS, INC.

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LICENSE AGREEMENT

This License Agreement ("Agreement") effective as of February 26, 2016 ("Effective Date") is made by and between Alba Therapeutics Corporation, a Delaware corporation ("Alba"), having an address at 100 International Drive, 23rd Floor, Baltimore, MD 21202, and Innovate Biopharmaceuticals, Inc., a Delaware corporation, having an address at 8601 Six Forks Road, Suite 400, Raleigh, NC 27615 ("Company").

ARTICLE 1. BACKGROUND

1.01 Alba and Company are parties to an Option Agreement, dated October 7, 2015, as amended, in which Alba granted an exclusive option to Company for the purchase of Alba's assets relating to Larazotide acetate and related compounds, which option was exercised by Company on January 15, 2016.

1.02 In lieu of entering into an asset purchase agreement, Alba and Company elected to enter into a license arrangement with respect to Alba's Assets (as defined below) and an accompanying sublicense arrangement (in the form of Exhibit C) with respect to that certain Restated Master License Agreement, dated as of July 1, 2005, by and between Alba and the University of Maryland, Baltimore.

1.03 In furtherance of such license arrangement and a potential eventual asset transfer, Alba desires to grant, and the Company desires to accept, an exclusive license to the Assets, upon the terms and subject to the conditions set forth in this Agreement.

1.04 Subject to certain conditions set forth herein, upon completion by the Company of certain clinical milestones Alba desires to sell, and the Company desires to purchase, the Assets pursuant to an asset purchase agreement incorporating terms mutually agreed upon herein.

ARTICLE 2. DEFINITIONS

In this Agreement, the following terms have the meanings set forth in this Article.

2.01 "Affiliate": Any entity that directly or indirectly controls, is controlled by, or is under common control with Company. "Control" means the right to exercise more than 50% of the voting rights of a controlled corporation, limited liability company, or partnership, or the power to direct or cause the direction of the management or policies of any other controlled entity.

2.02 "Assets": Intellectual Property and all other assets owned or controlled by Alba primarily related to the Licensed Product, including, without limitation, all inventory (including inventory identified on Exhibit A-1), contracts, books, records, files, regulatory filings and data related to the Licensed Product.

2.03 "CeD PRO Instrument": The Celiac Disease Patient Reported Outcome Instrument developed by Alba, including User Manual and Evidence Dossier, and any translations of the foregoing.

2.04 "Commercially Reasonably Efforts": With respect to the performance of development, manufacturing or commercialization activities with respect to the Licensed Products by Company or its Affiliates, the expenditure of efforts and resources consistent with the usual and commercially reasonable practice of Company in the exercise of its reasonable business discretion (but no less efforts and resources than a similarly-situated company would reasonably be expected to expend), with respect to development, manufacturing or commercialization of other products that are of similar market potential at a similar stage in their development or product life.

2.05 "Confidential Information": Information relating to the subject matter of the Licensed Product or Patent Rights which has not been made public and includes, without limitation, any documents, drawings, sketches, models, designs, data, memoranda, tapes, records, formulae and algorithms, given orally, in hard copy form, or in electronic form, which Company receives from Alba, or Alba receives from Company.

2.06 "Copyrights & Trademarks": The copyrights and trademarks listed on Exhibit A hereto.

2.07 "First Commercial Sale": The initial transfer of a Licensed Product for compensation by Company, an Affiliate or a Sublicensee to a Third Party. First Commercial Sale shall not include any transfer or disposition of a sample or for charitable purposes (including, without limitation, pursuant to an early access, compassionate use, named patient, indigent access or patient assistance program), or for preclinical, clinical or regulatory purposes.

2.08 "Improvement": An invention or discovery by Company directly related to the Patent Rights in the Licensed Field which is or may be patentable or otherwise protected under law, and is reasonably necessary for the practice of the Patent Rights by Alba or a third party.

2.09 "Intellectual Property": Patent Rights, Copyrights & Trademarks and Know-How.

2.10 "Know-How": All data, results, improvements, processes, methods, protocols, formulas, inventions, trade-secrets and other information, patentable or otherwise, which may include (but is not limited to) scientific, research and development, manufacturing know-how, pre-clinical, clinical, regulatory, manufacturing, safety, marketing, financial and commercial information or data which is owned or controlled by Alba and are necessary or useful to the research, development and/or commercialization of the Licensed Product.

2.11 "Licensed Field": All fields.

2.12 "Licensed Product(s)": Any pharmaceutical composition containing, consisting of, or comprising: (i) [***]; (ii) larazotide, including any salt or ester thereof including larazotide acetate; and (iii) to the extent not contemplated by the preceding clauses (i)-(ii), a compound for treating or preventing a condition, including but not limited to Celiac Disease, or its use in treatment or prevention of a condition, including but not limited to Celiac Disease, where the compound or method of use is covered by an issued Licensed Patent

2.13 "MAA": A marketing authorization application filed with the European Medicines Agency or any successor agency thereto ("EMA") to obtain regulatory approval for a new drug under the centralized EMA filing procedure or, if the centralized EMA filing procedure is not used, filed to obtain regulatory approval for a new drug using applicable procedures in accordance with applicable law in any European Union country.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

2.14 "NDA": A New Drug Application for purposes of the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, and the rules, regulations, guidelines, guidances and requirements promulgated thereunder, as may be in effect.

2.15 "Net Sales": The gross sales revenues and fees invoiced by Company, an Affiliate or a Sublicensee to independent Third Party purchasers who are not Affiliates, for the sale of Licensed Products, less the sum of the following: (a) credits, allowances, discounts and rebates to, and charge backs from the account of, such Third Party purchasers for spoiled, damaged, out-dated, rejected or returned Licensed Products; (b) actual freight and insurance costs incurred in transporting such Licensed Products to such Third Party purchasers; (c) cash, quantity and trade discounts and other price reductions; (d) sales, use, value-added and other direct taxes incurred (which term shall include any annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 allocable to such Licensed Product); (e) customs duties, surcharges and other governmental charges incurred in connection with the exportation or importation of such Licensed Products; and (f) the cost to Third Party purchasers of the devices for dispensing or administering such Licensed Products, as well as diluents or similar materials which accompany such Licensed Products as they are sold.

Net Sales do not include any resales of Licensed Product after its sale by Company, an Affiliate or a Sublicensee to a Third Party purchaser. In computing Net Sales, (1) no deductions from gross revenues and fees will be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed on the payroll by Company, its Affiliate(s) or Sublicensee(s), or for cost of collections, and (2) Licensed Products will be considered sold when invoiced.

2.16 "Patent Rights": Alba's interest in the patents and patent applications related to the Licensed Product, as further itemized in Exhibit B, including (i) patents and patents that may issue from the applications, (ii) all continuations, continuations-in-part, divisions, reissues, re-examinations or extensions of the foregoing, and (iii) and foreign counterparts of any of the foregoing.

2.17 "Phase 3 Trial": A controlled clinical study of a Licensed Product that is prospectively designed to demonstrate with statistical significance the efficacy and safety of the Licensed Product for use in a particular indication and that is sufficient to obtain regulatory approval by the FDA to market the Licensed Product in such indication.

2.18 "Sublicensee": A person or entity, including an Affiliate, to which Company sublicenses all or some of the Patent Rights or Assets.

2.19 "Third Party": Any entity or person other than Alba, Company, an Affiliate or a Sublicensee.

2.20 "Transferred IND" shall mean the Investigational New Drug Application (IND# 70,568) for larazotide acetate submitted on September 11, 2005 (Serial Number 0000).

ARTICLE 3. GRANT OF LICENSE; ASSIGNMENT OF CONTRACTS; OPTION

3.01 Alba hereby grants to Company, and Company accepts, an exclusive worldwide license under the Assets, including the Patent Rights, to conduct research and development and to make, have made, use, lease, offer to sell, sell and import the Licensed Products within the Licensed Field, anywhere in the world, for the term of this Agreement; provided, however, that with respect to the CeD PRO Instrument, such license shall be exclusive, subject only to licenses granted prior to the Effective Date which licenses are included in the Transferred Contracts.

3.02 During the term of this Agreement, Company may transfer its rights to an Affiliate consistent with this Agreement, provided Company is responsible for the obligations of its Affiliate relevant to this Agreement, including the payment of milestones, whether or not paid to Company by its Affiliate.

3.03 During the term of this Agreement, Company may grant sublicenses consistent with this Agreement, provided Company is responsible for the obligations of its Sublicensees relevant to this Agreement, including the payment of milestones, whether or not paid to Company by its Sublicensees, and provided further that in no event shall Company grant such a sublicense without first obtaining Alba's written consent, which consent shall not be unreasonably withheld. For clarification, no consent requirement shall be applicable after execution of the Asset Purchase Agreement.

3.04 Company will identify its Affiliates and its Sublicensees under this Agreement to Alba by name, address and field of sublicense (both as to geography and subject matter), and any other reasonable information necessary for Alba to conduct a meaningful audit under Section 9.01 below, except that Company reserves the right to redact any and all Confidential Information that is nonessential to any such Alba audit.

3.05 Alba hereby assigns to Company, and Company hereby assumes, Alba's rights and all obligations first arising after the Effective Date under (i) the contracts identified on Exhibit D attached hereto (the "Transferred Contracts") and (ii) the Transferred IND, and Alba shall have no liability thereunder for obligations first arising from and after the Effective Date, and the Company hereby agrees to indemnify Alba against any and all such liabilities thereunder; provided that, in the event this Agreement terminates for any reason, Company shall execute any and all documents necessary to assign back to Alba, and Alba shall assume back from Company, Alba's rights and obligations under the Transferred Contracts and the Transferred IND. Company shall not transfer, assign, modify, sublicense or terminate the Transferred Contracts or the Transferred IND without first obtaining Alba's written consent, which consent shall not be unreasonably withheld; provided, however, that Company may assign the Transferred Contracts and the Transferred IND in connection with an assignment of this Agreement pursuant to Article 12; and provided further that such assignments be subject to Alba's reversion rights as set forth in the immediately preceding sentence.

3.06 (a) Upon payment by Company of the first Milestone Payment (as defined in Section 5.01(b) below), and provided that Company has delivered to Alba reasonable evidence of sufficient financial resources necessary to complete Company's Phase 3 Trial in accordance with the Development Plan (as defined below), Company shall have an exclusive option to purchase (the "Company Option to Purchase") the Assets from Alba pursuant to the terms of a customary asset purchase agreement (an "Asset Purchase Agreement"), exercisable by Company's delivery to Alba, on or before the first (1st) anniversary of such first Milestone Payment, of a written notice informing Alba that Company is exercising its Company Option to Purchase (such notice, the "Company Exercise Notice").

(b) During the term of this Agreement, Alba shall have the right to sell (the "Alba Option to Sell") the Assets to Company pursuant to the terms of an Asset Purchase Agreement, exercisable by Alba's delivery to Company of a written notice informing the Company that Alba is exercising its Alba Option to Sell (such notice, the "Alba Exercise Notice").

(c) Upon either delivery by Company of the Company Exercise Notice or by Alba of the Alba Exercise Notice, Company and Alba agree to negotiate in good faith and execute an Asset Purchase Agreement within ninety (90) days following such delivery (the "Negotiation Period"). Should the Parties fail to enter into an Asset Purchase Agreement before the end of the Negotiation Period following Company's delivery of the Company Exercise Notice, this License Agreement will remain in effect.

(d) Notwithstanding the forgoing, such Asset Purchase Agreement shall include at least the following provisions:

1. a purchase price payable by Company to Alba for the purchase of the Assets that consists [***].

2. indemnification provisions substantially similar to the indemnification provisions set forth in this Agreement, subject to appropriate escrows, baskets and caps consistent with an asset purchase transaction;

3. the same diligence requirements set forth in this Agreement;

4. reporting provisions whereby Company shall provide reasonable updates regarding product development, clinical and regulatory matters sufficient to enable Alba to satisfy its obligations to its stockholders; and

5. for [***] ([***]) years following the effective date of the Asset Purchase Agreement, a covenant whereby Alba agrees it shall not directly or indirectly develop or commercialize any product that competes against the Licensed Product.

ARTICLE 4. COMPANY RESPONSIBILITIES

4.01 Company will use its Commercially Reasonable Efforts to bring one or more Licensed Products to market in accordance with the Development Plan (as defined below), subject in all cases to the following:

(a) Company has delivered to Alba prior to execution of this Agreement a confidential development plan (the "Development Plan") with respect to the development, manufacture and commercialization of the Licensed Product, a copy of which is attached hereto as Exhibit E. The Development Plan, and any reports or other information related thereto delivered by Company to Alba pursuant to Section 5.02(b) below, will be treated as Confidential Information by Alba.

(b) To the extent that the Company's responsibility for any aspect of the Development Plan is made the responsibility of an Affiliate or Sublicensee, Company retains its obligations to Alba as to this Article as if Company is solely responsible for that aspect.

4.02 Company agrees that any Licensed Products for use or sale in the United States will be manufactured substantially in the United States in accordance with the requirements of 35 U.S.C. Section 204 and 37 CFR 401.14(a)(i). In the event Company determines that compliance with this obligation is commercially impracticable, Company agrees that it will apply for a waiver of such obligation from the United States Government. In agreements with Affiliates and Sublicensees, Company will pass through this obligation. Company will use its best efforts to enforce this obligation and will promptly advise Alba of any known violations, or charges of violations, of this obligation.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

4.03 The use and disclosure of technical information acquired pursuant to this Agreement and the exercise of Patent Rights granted by this Agreement are subject to the export, assets, and financial control regulations of the United States of America, including, without limitation, restrictions under regulations of the United States that may be applicable to direct or indirect re-exportation of such technical information or of equipment, products, or services directly produced by use of such technical information. Company is responsible for taking any steps necessary to comply with such regulations.

ARTICLE 5. CONSIDERATION: PAYMENTS

In consideration of the license granted to Company:

5.01 (a) At execution of this Agreement, Company will pay to Alba a one-time, non-refundable license fee of Four Hundred Thousand Dollars ($400,000.00).

(b) In addition, Company shall make each of the following payments to Alba (each, a "Milestone Payment") upon the occurrence of each of the following corresponding events (each, a "Milestone Trigger"):

	Milestone Payment	Milestone Trigger
1.	$[***]	Dosing of first patient in first Phase 3 Trial
2.	$[***]	First Acceptance of an NDA or MAA for a Licensed Product
3.	$[***]	First Approval of an NDA or MMA for a Licensed Product
4.	$2,500,000.00	First Commercial Sale for a Licensed Product
5.	$[***]	First instance of annual Net Sales of Licensed Products in any calendar year exceeding $100,000,000.00
6.	$[***]	First instance of annual Net Sales of Licensed Products in any calendar year exceeding $500,000,000.00
7.	$[***]	First instance of annual Net Sales of Licensed Products in any calendar year exceeding $1,000,000,000.00
8.	$[***]	First instance of annual Net Sales of Licensed Products in any calendar year exceeding $1,500,000,000.00

(c) For the avoidance of doubt, if Company achieves more than one of the Milestone Triggers in the same calendar year, then Company shall, at the time prescribed in this Article 5, pay to Alba the applicable Milestone Payments for all of such Milestone Triggers achieved in such calendar year. For example, if Net Sales for a calendar year are $500,000,000.00 and Company has not previously paid to Alba the Milestone Payment applicable to Milestone Trigger 5 (but has previously paid to Alba the Milestone Payments applicable to Milestone Triggers 1, 2, 3 and 4), then Company shall pay $[***] to Alba (the sum of the Milestone Payments applicable to Milestone Triggers 5 and 6).

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

5.02 From and after the Effective Date:

(a) Company shall use its Commercially Reasonable Efforts to cause each Milestone Trigger to occur as promptly as practicable and shall not take any action or omit to take any action with the intent of circumventing or delaying any Milestone Trigger or Company's obligations set forth in this Article V.

(b) No later than forty five (45) days after the end of each calendar quarter (until Milestone Payment #3 has been made), Company shall provide Alba with a written report for such calendar quarter (each, a "Milestone Report"), in each case, setting forth in reasonable detail all material development, manufacturing and commercialization activities undertaken by or on behalf of Company, during such quarter with respect to the Licensed Product, as well as summary results of all pre-clinical or clinical studies related to Licensed Product completed during such quarter, including a review of activities as measured against the Development Plan, and shall otherwise keep Alba reasonably informed as to its activities and the status of its efforts with respect to the achievement of the Milestone Triggers, including, until the occurrence of the first Milestone Trigger, updates on Company's efforts to raise the capital necessary to accomplish the Development Plan. Company shall actively engage with Alba (including by making available Company's most senior research and development employee) to answer any questions regarding any Milestone Report and to provide such additional information and documents as Alba may reasonably request with respect thereto.

(c) If a Milestone Trigger has been achieved during a calendar quarter, the Milestone Report for such calendar quarter shall indicate such achievement.

(d) Without limiting clause (b) above, Company shall (until all of the Milestone Payments have been made), upon at least ten (10) business days' prior notice, permit an independent third party accounting firm reasonably acceptable to both parties reasonable access during normal business hours to examine such records at the facilities where such records are customarily kept, as may be necessary for the sole purpose of verifying the calculation and reporting of Net Sales. Such examination shall occur no more frequently than once each calendar year and shall be paid for by Alba, unless the auditor determines that Company undercalculated Net Sales by more than $[***], in which case such examination shall be paid for by Company. The independent accounting firm may only disclose to Alba (i) whether a Milestone Trigger has been achieved or (ii) that Company undercalculated Net Sales.

5.03 Company shall pay each Milestone Payment with respect to a Development Milestone Trigger to Alba within thirty (30) days after providing to Alba notice of the achievement of the applicable Milestone Trigger (whether in a Milestone Report or otherwise). Interest is due on any Milestone Payment payable to Alba under this Agreement. The interest rate is the prime rate plus [***] percent simple interest per annum accruing from the due date.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

ARTICLE 6. DATA

6.01 Nothing herein shall be construed to require either party to disclose or deliver to the other party any information or communication that is considered by the disclosing party to be protected by the attorney-client privilege, or is considered by the disclosing party to be attorney work product, without the express written consent of the disclosing party. In no event shall this clause be deemed to permit (i) Alba to withhold any pre-clinical or clinical data or (ii) Company to withhold any data or information required to be included in any Milestone Report prepared for, and delivered to, Alba pursuant to Section 5.02(b) above.

ARTICLE 7. PATENT PROSECUTION

7.01 Company, at company's expense shall file, prosecute and maintain all patents and patent applications specified in Exhibit B. Company shall have control over all patent matters, provided however, that Company shall allow Alba an opportunity to comment and advise Company on decisions that diminish or limit the scope of any patent or application. If Company elects to abandon any patent application (except for purposes of filing a continuation application) or patent in any country, Company shall notify Alba in writing at least thirty (30) days prior to any filing or payment due date or any other deadline that requires action to avoid loss of rights and thereafter, Alba shall have the right to control the filing, prosecution, and/or maintenance of such patent application or patent in such country at its own expense. By written notification to Alba at least thirty (30) days in advance of any filing or response deadline, or fee due date, company may elect not to have a particular patent application maintained in any particular country or not to pay expenses associated with filing, prosecuting or maintaining a particular patent application or patent, provided that company pays for all costs incurred up to Alba's receipt of such notification. Upon such notification, Alba may file, prosecute and/or maintain such patent applications or patent in such country at its own expense and for its own benefit, and any rights or license granted hereunder held by company, an affiliate or sublicensee relating to such patent application or patent in such country shall terminate.

ARTICLE 8. CONFIDENTIALITY

8.01 Knowingly or inadvertently, either party may disclose to the other certain Confidential Information. Disclosures by Alba are deemed to refer to disclosures by any Alba officers, directors, employees, consultants or agents. Disclosures by Company are deemed to refer to disclosures by Company officers, directors, employees, consultants or agents. Confidential Information may be disclosed only in accordance with the provisions of this Article.

8.02 Except as hereafter specifically authorized in writing by the disclosing party, the receiving party will not disclose or use the Confidential Information for a period of [***] years after the date of receipt of Confidential Information.

8.03 These obligations of non-disclosure and nonuse do not apply to any Confidential Information which the receiving party can demonstrate by reliable written evidence:

(a) was generally available to the public at the time of disclosure to the receiving party; or

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[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

(b) was already in the possession of the receiving party at the time of the disclosure, other than pursuant to a confidential disclosure agreement between the parties and not due to any unauthorized act by the receiving party; or

(c) was developed by the receiving party prior to the disclosure; or

(d) the receiving party is required by law to disclose.

8.04 These obligations of non-disclosure and nonuse will not continue to apply to any Confidential Information which the receiving party can demonstrate by reliable written evidence:

(a) has become generally available to the public other than through a breach of this Agreement by the receiving party after disclosure;

(b) has been acquired by the receiving party on a nonconfidential basis from any third party having a lawful right to disclose it to the receiving party; or

(c) corresponds to information developed by the receiving party independent of and with no reliance upon the disclosing party's Confidential Information.

8.05 Each party will use that level of care to prevent the use or disclosure of the other party's Confidential Information as it exercises in protecting its own Confidential Information, which in no event will be less than a reasonable standard of care.

8.06 All Confidential Information will be clearly marked as confidential by the disclosing party and, if not in written or tangible form when disclosed, will be indicated as confidential upon disclosure and then summarized in writing and so marked as confidential within 30 days after disclosure to the receiving party.

8.07 Notwithstanding the foregoing, Company, its Affiliates and its Sublicensees are permitted to disclose and use the Confidential Information to the extent reasonably necessary to exercise Company's license or sublicenses hereunder, or to comply with Federal reporting requirements, provided that any disclosure is made subject to written confidentiality restrictions consistent with those accepted by Company in this Agreement. During the Term and after execution of the Asset Purchase Agreement, any Confidential Information related to Licensed Product shall be deemed to constitute Confidential Information of Company.

8.08 Upon termination of this Agreement (unless terminated by virtue of execution of the Asset Purchase Agreement), (i) Company will return to Alba all material which is Confidential Information of Alba, together with all copies and other forms of reproduction, except that a single archive copy may be kept in Company's legal files, and (ii) Alba will return to Company all material which is Confidential Information of Company, together with all copies and other forms of reproduction, except that a single archive copy may be kept in Alba's legal files. Each party agrees that termination of this Agreement does not alter the [***] year obligation of confidentiality set forth in Section 8.02.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

ARTICLE 9. [INTENTIONALLY OMITTED]

ARTICLE 10. INFRINGEMENT

10.01 Alba and Company agree to notify each other promptly of each infringement or possible infringement of the Patent Rights of which either party becomes aware.

10.02 Company may (a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably valid claims in the Patent Rights licensed to Company; (b) in any such suit, enjoin infringement and collect for its use damages, profits, and awards of whatever nature recoverable for such infringement; and (c) settle any claim or suit for infringement of the Patent Rights. Company may not compel Alba to initiate or join in any such suit for patent infringement. Company may request Alba to initiate or join in any such suit if necessary to avoid dismissal of the suit. If Alba is made a party to any such suit, Company will reimburse and indemnify Alba for any costs, expenses, or fees which Alba incurs as a result of its joinder. In all cases, Company agrees to keep Alba reasonably apprised of the status and progress of any litigation.

10.03 If an infringement action or a declaratory judgment action alleging invalidity or non-infringement of any of the Patent Rights is brought against Company or raised by way of counterclaim or affirmative defense in an infringement suit brought by Company under Section 10.02, Company may (a) defend the suit in its own name, at its own expense, and on its own behalf for presumably valid claims in the Patent Rights; (b) in any such suit, ultimately enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for such infringement; and (c) settle any claim or suit for damages or a declaratory judgment involving the Patent Rights, including the granting of further licenses on sublicenses, provided that Company does not admit Alba's infringement or concede invalidation of any Patent Rights, without Alba's prior written consent, respectively. Alba consent will not be unreasonably withheld. Company may not compel Alba to initiate or join in any such suit. Company may request Alba to initiate or join in any such suit if necessary to avoid dismissal of the suit. If Alba is made a party to any such suit, Company will reimburse and indemnify Alba for any costs, expenses, or fees which it incurs as a result of its joinder. In all cases, Company agrees to keep Alba reasonably apprised of the status and progress of any litigation.

10.04 Company will not settle any action described in Section 10.02 or 10.03 without first notifying Alba. In any action under Sections 10.02 or 10.03, the expenses of Company and Alba, including costs, fees, attorney fees, and disbursements, will be paid by Company.

10.05 Alba will cooperate reasonably with Company in connection with any action under Sections 10.02 or 10.03. Alba agrees to provide prompt access to all necessary documents and to render reasonable assistance in response to requests by Company.

10.06 Alba has a continuing right to intervene in a suit initiated by Company under Section 10.02 or in a declaratory judgment action involving the Patent Rights brought against Company under Section 10.03. In either case, if Alba chooses to intervene, Alba will be responsible for its litigation expenses and will be entitled to all recoveries which it obtains for itself as a result of its intervention.

10.07 If Company desires to initiate a suit for patent infringement under Section 10.02, Company will notify Alba in writing within 90 days after giving or receiving notice of infringement under Section 10.01. If Company fails to notify Alba of its intent to initiate suit within the 90 day period or if Company notifies Alba that it does not intend to initiate suit, Alba may initiate suit at its own expense. In such case, Alba is entitled to all recoveries from such action.

10.08 If an infringement action or a declaratory judgment action alleging invalidity or non-infringement of any of the Patent Rights is brought against Company or raised by way of counterclaim or affirmative defense in an infringement suit brought by Company as described in Section 10.02, Company will notify Alba whether Company intends to respond in opposition to such legal action within 15 days after Company's receipt of notice of the filing of such action. If Company fails to notify Alba of its intent to respond in opposition to such legal action within the 15 day period, or if Company notifies Alba that it does not intend to oppose the action, Alba may respond to the legal action at Alba's expense. In such case, Alba is entitled to all recoveries from such action.

10.09 Company will cooperate reasonably with Alba in connection with any action described in Sections 10.07 or 10.08. Company agrees to provide prompt access to all necessary documents and to render reasonable assistance in response to requests by Alba.

ARTICLE 11. TERM AND TERMINATION

11.01 Unless sooner terminated in accordance with any of the succeeding provisions of this Article 11, this Agreement will continue in full force and effect. Upon payment of Milestone Payment 4, the licenses granted herein shall thereafter be perpetual and irrevocable. Upon payment of Milestone Payment 8, the licenses granted herein shall thereafter be perpetual, irrevocable and royalty free.

11.02 Should Company fail to pay Alba any sum due and payable under this Agreement prior to and including Milestone Payment 4, Alba may terminate this Agreement on thirty (30) days written notice, unless Company pays Alba within the thirty (30) day period all delinquent sums together with interest due and unpaid. Upon expiration of the thirty (30) day period, if Company has not paid all sums and interest due and payable, the parties will enter into a thirty (30) day Cure Period during which time, both parties will attempt to resolve the non-payment. If no resolution is reached at the end of the Cure Period, then the rights, privileges, and licenses granted under this Agreement will terminate.

11.03 Prior to the First Commercial Sale of a Licensed Product to a Third Party, Company is considered diligent with regard to development of a Licensed Product as long as Company updates and reports progress against the Development Plan in its Milestone Reports and as long as Company continues to use Commercially Reasonable Efforts pursuant to Section 4.01 above to accomplish the Development Plan as it relates to Licensed Products.

11.04 If Alba reasonably believes that Company is not diligent in development of Licensed Product based upon the criteria set forth in Section 11.03, then Alba may assert a breach and its termination rights under Section 11.05 below and invoke the dispute resolution procedures in Section 18.

11.05 In the event that prior to the First Commercial Sale of a Licensed Product to a Third Party Company, an Affiliate or a Sublicensee breaches Sections 3.02, 3.03, 3.04, 4.01, 5.02, 5.03, 10.04(a), 12.01, 15.02, 16.01 or 16.02, Alba may terminate this Agreement upon 90 days written notice to Company. However, if the breach is corrected within the 90-day period and Alba is reimbursed for all damages directly resulting from the breach, this Agreement will continue in full force and effect and Alba will so notify Company in writing.

11.06 Expiration or termination of this Agreement does not relieve either party of any obligation for payment and reporting which arises before expiration or termination including obligations under Articles 5 and 7 (but only for expenses incurred before termination). Articles 2, 10, 13, 14, 15, 16, 17, and 18 and Sections 6.03, 11.07, 11.08 and 19.09 will survive expiration or termination. Article 8 and Sections 19.02 will survive expiration or termination and will expire in accordance with their terms. Other sections of this Agreement will be effective after expiration or termination where that intent is clear from the content of those sections

11.07 Upon termination of this entire Agreement pursuant to Section 11.05, any Sublicensee not in default may seek a license directly from Alba to practice Patent Rights within the licensed field set out in its sublicense and upon the consideration stated in its sublicense to the extent such consideration has not previously been paid to Company. Alba will permit a Sublicensee not in default to continue use of Patent Rights for a period of up to 60 days (the "Continuation Term") after termination of this Agreement while Alba and the Sublicensee negotiate, such license to be consistent with the terms of this Agreement subject to appropriate amendments of Article 5 and relevant definitions to substitute the consideration and field of use provisions from the sublicense. Should Alba and the Sublicensee fail to agree upon an amendment within the Continuation Term, they will submit the definition and consideration provisions in dispute between them to commercial arbitration for resolution, and include the resulting provisions in a license. Prior to the Continuation Term, and in consideration of the opportunity to enter into a license agreement with Alba, a Sublicensee seeking a license from Alba must tender to Alba a written agreement to pay running royalties and milestone payments to Alba with respect to Net Sales during the Continuation Term and any subsequent period of arbitration upon the terms that running royalties and milestones due Alba from the Company would be calculated in this Agreement, or to pay running royalty and milestone payments at the rate provided in the sublicense, whichever is greater.

11.08 Upon the termination of this Agreement (unless terminated by virtue of execution of the Asset Purchase Agreement), and notwithstanding anything to the contrary in Section 8.09 above, at Alba's request, Company will (a) execute a document acknowledging the license rights that have expired or terminated (b) execute any and all documents necessary to assign all Company Improvements to Alba and (c) make a good faith effort to transfer to Alba any other data, information or results, relating to the Licensed Products, obtained by Company during the term of this Agreement, whether or not the same constitutes Company Confidential Information.

ARTICLE 12. ASSIGNABILITY

12.01 Company may assign this Agreement to an Affiliate or to a successor to all or substantially all of Company's assets or business related to Licensed Product. Company may not otherwise assign or transfer this Agreement without the prior written consent of Alba, which will not be unreasonably withheld.

12.02 Alba may assign this Agreement to a successor-in-interest but Alba may not otherwise assign or transfer this Agreement without the prior written consent of Company, which will not be unreasonably withheld.

ARTICLE 13. APPLICABLE LAW; WAIVER

13.01 This Agreement is made and construed in accordance with the laws of the State of Delaware without regard to choice of law issues, except that all questions concerning the construction or effect of patents will be decided in accordance with the laws of the country in which the particular patent concerned has been granted.

13.02 Each Party submits itself to the jurisdiction and venue of any state of federal court located in the State of Delaware.

13.03 Alba and Company waive their rights to trial by jury as to any litigation between them relating to this Agreement.

ARTICLE 14. INTEGRATION AND INTERPRETATION

14.01 This Agreement, together with any Exhibits specifically referenced and attached, embodies the entire understanding between Company and Alba with respect to the subject matter hereof. There are no contracts, understandings, conditions, warranties or representations, oral or written, express or implied, with reference to the subject matter of this Agreement that arc not merged in this Agreement.

14.02 This Agreement is negotiated as an arm's-length business transaction. Draftsmanship will not be taken into account in construing the Agreement.

14.03 If any condition or provision in any Article of this Agreement is held to be invalid or illegal or contrary to public policy by a court of competent jurisdiction from which there is no appeal, this Agreement will be construed as though the provision or condition did not appear. The remaining provisions of this Agreement will continue in full force and effect.

ARTICLE 15. REPRESENTATIONS AND WARRANTIES

15.01 Alba hereby represents that, as of the date of execution by the officer (a) Alba has full right, title, and interest in and to the Patent Rights identified in Exhibit B (unless otherwise noted as co-owned on Exhibit B); (b) to the knowledge of the executing Alba officer, the Patent Rights identified in Exhibit B are not the subject matter of any currently pending claims, actions or litigation involving Alba, and Alba has not been informed of any related matters or litigation contemplated either by Alba or any Third Party; (c) Alba is unaware that any person disputes inventorship or ownership of Patent Rights as described in this Agreement; (d) to the knowledge of the executing Alba officer, the Transferred Contracts are in full force and effect, binding and enforceable upon Alba and the other parties thereto; (e) Alba and each other party to Transferred Contracts are in material compliance therewith; (f) to the knowledge of the executing Alba officer, Alba all pre-clinical studies conducted by or on behalf of Alba with respect to Licensed Product were conducted in compliance with all applicable laws and standards applicable to pharmaceutical development; (g) to the knowledge of the executing Alba officer, Alba has disclosed to Company prior to the Effective Date all preclinical and clinical data related to Licensed Product known to Alba; and (h) to the knowledge of the executing Alba officer, neither Alba nor any of its Affiliates nor any Third Party owns or controls any intellectual property related to Licensed Products which is not licensed to Company hereunder or under the accompanying Sublicense with the University of Maryland. Alba warrants that the officer of Alba executing this Agreement is authorized to do so on behalf of Alba. ALBA EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, AND PATENT VALIDITY, WITH RESPECT TO PATENT RIGHTS. ALBA EXPRESSLY DISCLAIMS ANY RELIANCE ON ANY AND ALL OF ALBA'S CLINICAL OR TOXOCOLOGY TRIAL DATA AND RESULTS, AND COMPANY HEREBY ACKNOWLEDGES THAT ALBA SHALL HAVE NO LIABILITY FOR COMPANY'S DECISION TO ADVANCE THE LICENSED PRODUCT IN RELIANCE ON SUCH DATA AND RESULTS.

15.02 Company hereby represents and warrants to Alba that: (a) Company has full legal right, power and authority to execute, deliver and perform its obligations under this Agreement; (b) the execution, delivery and performance by Company of this Agreement do not contravene or constitute a default under any provision of applicable law or of any agreement, judgment, injunction, order, decree, or other instrument binding upon Company; and (c) the officer of the Company executing this Agreement has been authorized by the Company's board of directors or governing body to execute this Agreement as the act of the Company.

ARTICLE 16. CLAIMS, INDEMNIFICATION AND INSURANCE

16.01 Company warrants and represents that it maintains comprehensive liability insurance coverage for itself, its officers, employees and agents, in the minimum amounts of $[***] per claim and $[***] aggregate (inclusive of umbrella coverage), applicable to bodily injury and property damage. Prior to the initiation of any human trials in any geographical location with any products, processes, or protocols developed either by Company, its Affiliates, or Sublicensees or their officers, servants, or agents, or by Third Parties acting on behalf of or under authorization from Company, its Affiliates or Sublicensees, using licensed Patent Rights, the Company will establish and maintain Product & Clinical Trials Liability insurance coverage in the amount of $[***] per claim and $[***] aggregate. Company warrants that its liability insurance will cover contractually assumed obligation for product liability claims referred to in Section 16.03, when/if human clinical trials are commenced. Alba acknowledges that Company's liability insurance will not cover indemnity claims related to patent infringement referred to in Section 16.03. A certificate evidencing the required insurance coverage will be delivered to Alba: (i) at or before execution of this Agreement; (ii) each time there is a change in Company's insurance coverage; and (iii) each time Company's insurance coverage is renewed. Company agrees to require its insurance carrier(s) to notify Alba within 15 days prior to cancellation of Company's insurance coverage, except in the case of cancellation for nonpayment of premium, where 10 days advance notice will be provided. If Company does not secure liability insurance written on an occurrence basis, but instead secures liability insurance written on a claims-made basis, Company warrants that it will purchase extending reported coverage or otherwise provide insurance satisfying its obligations hereunder for a period of not less than [***] years following termination of this Agreement.

16.02 (a) Company will defend, indemnify, and hold harmless Alba, Alba Personnel and Alba Affiliates, and their, officers, employees, and agents (each individually an "Alba Party" and all, collectively "Alba Parties"), against any and all claims, costs or liabilities, including attorney's fees and court costs at trial and appellate levels, for any loss, damage, personal injury, or loss of life:

1. caused by the actions of Company, its Affiliates, or Sublicensees, or their officers, servants, or agents, or Third Parties acting on behalf of or under authorization from Company, its Affiliates or Sublicensees, in the performance of this Agreement;

2. arising out of use of licensed Patent Rights by Company, its Affiliates, or Sublicensees or their officers, servants, or agents, or by any Third Party acting on behalf of or under authorization from Company, its Affiliates, or Sublicensees; or

3. arising out of use by a Third Party of products, processes, or protocols developed either by Company, its Affiliates, or Sublicensees or their officers, servants, or agents, or by Third Parties acting on behalf of or under authorization from Company, its Affiliates or Sublicensees, using licensed Patent Rights, provided such use was consistent with any instructions, protocols or supervision provided by Company.

(b) Alba will defend, indemnify, and hold harmless Company, Company Personnel and Company Affiliates, and their officers, employees, and agents (each individually a "Company Party" and all, collectively "Company Parties"), against any and all claims, costs or liabilities, including attorney's fees and court costs at trial and appellate levels, for any loss, damage, personal injury, or loss of life:

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

1. caused by the actions of Alba or its Affiliates or their officers, servants, or agents, or Third Parties acting on behalf of or under authorization from Alba or its Affiliates or Sublicensees;

2. arising out of use of licensed Patent Rights by Alba, its Affiliates or their officers, servants, or agents, or by any Third Party acting on behalf of or under authorization from Alba or its Affiliates;

3. arising out of use, prior to the Effective Date, by a Third Party of products, processes, or protocols developed either by Alba or its Affiliates or their officers, servants, or agents, or by Third Parties acting on behalf of or under authorization from Alba or its Affiliates, using licensed Patent Rights, provided such use was prior to the Effective Date and consistent with any instructions, protocols or supervision provided by Alba.

(c) Company's agreement to defend, indemnify and hold harmless a Alba Party is conditioned upon and Alba's agreement to defend, indemnify and hold harmless a Company Party is conditioned upon:

1. Alba or Company promptly notifying the other in writing after it receives notice of a claim, and

2. the Alba Party or Company Party seeking indemnification fully cooperating with Alba and the Company in the defense of the claim.

(d) Company's agreement to defend, indemnify and hold harmless a Alba Party will not apply to any claim, cost, or liability attributable to the negligent act or willful misconduct of the Alba Party or a Third Party acting outside the direction or control of Company. Alba's agreement to defend, indemnify and hold harmless a Company Party will not apply to any claim, cost, or liability attributable to the negligent act or willful misconduct of the Company Party or a Third Party acting outside the direction or control of Alba.

16.03 Alba and Company further agree that nothing in this Agreement will be interpreted as a denial to either party of any remedy or defense available to it under the laws of the State of Delaware.

ARTICLE 17. ADVERTISING AND PUBLICITY

17.01 Neither party will use the name of the other or any of its employees or personnel, or any adaptation thereof, in any advertising, promotional, or sales literature without prior written consent obtained from the other party. Either party may publicize the fact that the parties have made this Agreement.

ARTICLE 18. DISPUTE RESOLUTION

If a dispute between the parties related to this Agreement arises, either party, by notice to the other party, may have the dispute referred to the parties' respective officers designated below, or their successors, for attempted resolution by good faith negotiations within 30 days after the notice is received. The designated officers are as follows:

For Company:	Chief Executive Officer
For Alba:	Chief Executive Officer

In the event the designated officers are not able to resolve the dispute within this 30 day period, or any agreed extension, they will confer in good faith with respect to the possibility of resolving the matter through mediation with a mutually acceptable Third Party or a national mediation organization. The parties agree that they will participate in any mediation sessions in good faith in an effort to resolve the dispute in an informal and inexpensive manner. All expenses of the mediator will be shared equally by the parties. Any applicable statute of limitations will be tolled during the pendency of a mediation initiated under this Agreement. Evidence of anything said or any admission made in the course of any mediation will not be admissible in evidence in any civil action between the parties. In addition, no document prepared for the purpose of, or in the course of, or pursuant to, the mediation, or copy thereof, will be admissible in evidence in any civil action between the parties. However, the admissibility of evidence will not be limited if all parties who participated in the mediation consent to disclosure of the evidence.

ARTICLE 19. MISCELLANEOUS

19.01 No license or right is granted by implication or otherwise with respect to any patent application or patent owned by either party, unless specifically set forth in this Agreement.

19.02 Neither party is liable for failure or delay in performing any of its obligations under this Agreement if the failure or delay is required in order to comply with any governmental regulation, request or order, or necessitated by other circumstances beyond the reasonable control of the party so failing or delaying, including but not limited to Acts of God, war (declared or undeclared), insurrection, fire, flood, accident, labor strikes, work stoppage or slowdown (whether or not such labor event is within the reasonable control of the parties), or inability to obtain raw materials, supplies, power or equipment necessary to enable a party to perform its obligations. Each party will: (a) promptly notify the other party in writing of an event of force majeure, the expected duration of the event and its anticipated effect on the ability of the party to perform its obligations; and (b) make reasonable efforts to remedy the event of force majeure.

19.03 All notices, consents and other communications required or allowed under this Agreement must be in writing and are effective upon receipt: (a) when delivered by hand; or (b) when received by the addressee after being mailed by registered or certified mail (air mail if mailed overseas), return receipt requested; or (c) when received by the addressee, by delivery service (return receipt requested), in each case addressed to the party at its address set forth below (or to another address that a party may later designate by notice to the other party):

If to Alba:	Alba Therapeutics Corporation 100 International Drive, 23rd Floor Baltimore, MD 21202
Copy to:	Morgan, Lewis & Bockius LLP One Federal Street Boston, MA 02110 Attn: and Mark Hayman, Esq.
If to Company:	Innovate Biopharmaceuticals, Inc. 8601 Six Forks Road Suite 400 Raleigh, NC 27615

Copy to: Hutchison PLLC
3110 Edwards Mill Road, Suite 300
Raleigh, NC 27612
Attn: Bill Wofford, Esq.

19.04 This Agreement, including Exhibits, may not be amended, nor may any right or remedy of either party be waived, unless the amendment or waiver is in writing and signed by a duly authorized representative of each party.

19.05 A failure or delay by a party in exercising any of its rights or remedies under this Agreement does not constitute a waiver of the rights or remedies, nor does any single or partial exercise of any right or remedy preclude any other or further exercise thereof or the exercise of any other right or remedy. The rights and remedies of the parties provided in this Agreement are cumulative and not exclusive of any rights or remedies provided by law.

19.06 Alba and Company are not (and nothing in this Agreement may be construed to constitute them as) partners, joint venturers, agents, representatives or employees of the other, nor is there any status or relationship between them other than that of independent contractors. Neither party has any responsibility nor liability for the actions of the other party except as specifically provided in this Agreement. Neither party has any right or authority to bind or obligate the other party in any manner or make any representation or warranty on behalf of the other party.

19.07 Unless otherwise provided, all costs and expenses incurred in connection with this Agreement will be paid by the party which incurs the cost or expense, and the other party has no liability for such cost or expense.

19.08 This Agreement is not intended to create, and does not create, enforceable legal rights as a third party beneficiary or through any other legal theory on the part of any Section 16.02.

19.09 This Agreement is signed in duplicate originals. The headings used in this Agreement are for convenience of reference only and do not affect the meaning or construction of this Agreement.

19.10 Further Assurance. Each Party shall duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents, and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement. Without limiting the generality of the foregoing, in the

[signature page to follow]

The parties have caused this Agreement to be executed by their duly authorized representatives on the dates indicated below.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Jay P Madan
Name: Jay P Madan
Title: President

ALBA:

ALBA THERAPEUTICS CORPORATION

By: /s/ Wendy Perrow
Name: Wendy Perrow
Title: CEO

[Signature Page to License Agreement]

EXHIBIT A

COPYRIGHTS & TRADEMARKS

A. Celiac Disease Patient Reported Outcome (CeD PRO) Instrument

1. Certificate of Registration of the Celiac Disease PRO Questionnaire, Registration Number TXu-780-192, effected date of registration October 13, 2011

2. Copyright Certificate of Registration No. TXu-780-192, letter regarding the Registration of Celiac Disease PRO Questionnaire, dated February 21 2012

B. Trademark Status Chart

[***]

C. Wheat Character

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

EXHIBIT A-1

INVENTORY

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

EXHIBIT B

PATENT RIGHTS

(*co-owned with University of Maryland, Baltimore)

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

EXHIBIT C

FORM OF UMD SUBLICENSE

[Filed as Exhibit 10.1 to the Form 10-K for the year ended December 31, 2017]

EXHIBIT D

TRANSFERRED CONTRACTS

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

EXHIBIT E

DEVELOPMENT PLAN

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

Exhibit 10.3

ASSET PURCHASE AGREEMENT

This **Asset Purchase Agreement** (this "**Agreement**") is made and entered into as of December 23rd, 2014 ("**Effective Date**") between **Innovate Biopharmaceuticals Inc.**, a Delaware corporation, with offices at 8601 Six Forks Road, Suite 400, Raleigh, North Carolina 27615, ("**Innovate**") and **Repligen Corporation**, a Delaware corporation with offices at 41 Seyon Street, Building 1, Suite 100, Waltham, MA 02453 ("**Repligen**"). Repligen and Innovate shall also be referred to herein individually as "**Party**" and collectively as "**Parties**".

WHEREAS, Repligen owns certain assets (as more fully defined below, the "**Assets**") relating to SecreFlo, a synthetic human secretin, and its use to improve visualization of pancreatic duct abnormalities when used in combination with magnetic resonance imaging; and

WHEREAS, Innovate and Repligen desire to enter into this Agreement under which Innovate will acquire all of the Assets.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and premises contained in this Agreement, the receipt and sufficiency of which are hereby expressly acknowledged, the Parties hereto agree as follows:

1. DEFINITIONS.

In this Agreement, the following words and expressions shall be construed as follows:

1.1 "**Affiliate**" means any person, corporation, company, partnership, joint venture, firm or other entity which controls, is controlled by or is under common control with a Party. For purposes of this Section 1.1, "control" will mean (i) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) (or such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction) of the stock or shares entitled to vote for the election of directors and (ii) in the case of non-corporate entities, direct or indirect ownership of at least fifty percent (50%) of the equity interest with the power to direct the management and policies of such non-corporate entities.

1.2 "**Assets**" means (i) all clinical and non-clinical data, reports, know how, regulatory filings (including for orphan designation) and approvals to the extent still valid and transferable, and all intangible property rights to the extent still valid and transferable, including any domain names, trade secrets, formulae, processes, designs, manufacturing know how, and any other intellectual property, in each case, as contained in the electronic data room maintained by Repligen and shared with Innovate, and (ii) laboratory notebooks or files located on the premise at Repligen, in each of (i) and (ii), only to the extent related to synthetic human secretin and Controlled by Repligen. The assets described in (i) shall be collectively referred to as the "Electronic Files", and the assets described (ii) shall be collectively referred to as the "Physical Files".

1.3 **"Commercially Reasonable Efforts"** means, in reference to a Party's obligation to perform or achieve a specified obligation or goal with respect to a particular product, efforts that are comparable in quality and scope to those efforts that are generally used by such Party to perform or achieve a comparable obligation or goal with respect to a product in respect of which such Party owes no royalties or similar third party payments, which has the same regulatory requirements or status (for example, requires a prescription), is at a comparable stage of development or product life to the relevant product, and that has similar market potential to the relevant product, taking into account relative safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the product and relevant regulatory circumstances. Without limiting the foregoing, Commercially Reasonable Efforts require that a Party: (i) devote appropriate resources and personnel with an appropriate level of education, experience and training for the relevant obligation; (ii) promptly assign responsibility for the relevant obligation to specific employees and/or contractors who are held accountable for progress and monitor such progress on an on-going basis, (iii) set and consistently seek to achieve specific and meaningful objectives and timelines for carrying out such obligation, and (iv) consistently make and implement decisions and allocate resources designed to advance progress with respect to relevant objectives and timelines.

1.4 "**Confidential Information**" has the meaning set forth in Section 9 of this Agreement.

1.5 "**Control**" or "**Controlled**" means with respect to any Information and/or Patents, the possession by a Party of the ability to assign or to grant a license or sublicense of such Information and/or Patents as provided herein without violating the terms of any agreement or arrangement between such Party and any third party.

1.6 "**Dollar**" means a U.S. dollar, and "$" shall be interpreted accordingly.

1.7 "**Executive Officer**" means, with respect to Repligen, its Chief Executive Officer, and with respect to Innovate, its Chief Executive Officer.

1.8 "**First Commercial Sale**" means, with respect to a particular Product in a particular country, the first arms-length sale to a Third Party of such Product in such country after Regulatory Approval has been obtained in such country. First Commercial Sale shall not include any transfer or disposition of a sample or for charitable purposes (including, without limitation, pursuant to an early access, compassionate use, named patient, indigent access or patient assistance program), or for preclinical, clinical or regulatory purposes.

1.9 "**Generic Competition**" means, with respect to a particular Product, when there is one or more products being sold that are Generic Products with respect to such Product. For clarity, [***].

1.10 "**Generic Product**" means with respect to a particular Product, a diagnostic product that (a) contains as active ingredient secretin (or any derivative or variant or similar form of such agent); (b) is approved for use in the United States pursuant to a regulatory approval process governing approval of generic, interchangeable or biosimilar biologics based on the then-current standards for regulatory approval in the United States, whether or not such regulatory approval was based in whole or part upon clinical data generated by either Innovate or Repligen pursuant to this Agreement or was obtained using an abbreviated, expedited or other process; and (c) is sold in the United States by any Third Party who has not obtained the right or access to such product (through (sub)license, subcontract or chain of distribution) from Innovate or any of its Affiliates or licensees and did not purchase such product in a chain of distribution that included Innovate or any of its Affiliates or licensees. For clarity, [***] shall not constitute Generic Product.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

1.11 "**Governmental Authority**" means any multi-national, federal, state, local, municipal, provincial or other governmental authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).

1.12 "**Information**" means any data, results, technology, business information and information of any type whatsoever, in any tangible or intangible form, including, without limitation, know-how, trade secrets, practices, techniques, methods, processes, inventions, improvements, developments, specifications, formulations, formulae, materials or compositions of matter of any type or kind (patentable or otherwise), software, algorithms, marketing reports, expertise, technology, test data (including pharmacological, biological, chemical, biochemical, toxicological, preclinical and clinical test data), analytical and quality control data, stability data, other study data and procedures.

1.13 "**Laws**" means any law, statute, rule, regulation, ordinance or other pronouncement having the effect of law of any federal, national, multinational, state, provincial, county, city or other political subdivision, domestic or foreign.

1.14 "**Net Sales**" means, with respect to a particular time period, the total amounts invoiced by Innovate, its Affiliates and their respective licensees for sales of Products made during such time period to unrelated Third Parties, less the following deductions to the extent actually allowed or incurred with respect to such sales:

(a) reasonable and customary discounts, including cash and quantity discounts, charge-back payments, administrative fees incurred directly in such discounting, and rebates actually granted to trade customers and distributors;

(b) reasonable and customary credits or allowances actually granted for damaged, outdated, spoiled, returned or rejected Products, including, without limitation, in connection with recalls;

(c) sales and excise taxes, tariffs, duties or other governmental charges (other than income taxes) levied on, absorbed or otherwise imposed on the manufacture or sales of Products;

(d) freight, insurance, data, administrative, inventory management and nursing charges or other fees related to handling and distribution of Products (to the extent not paid by the Third Party customer);

(e) credits and allowances made for wastage replacement and indigent or similar programs; and

(f) reasonable allowances for bad debts as reconciled to actual experience at least annually.

Each of the deductions set forth above shall be reasonable and customary, and in accordance with United States Generally Accepted Accounting Principles (GAAP). Notwithstanding the foregoing, amounts billed by Innovate, its Affiliates, or their respective licensees for the sale of Products among Innovate, its Affiliates or their respective licensees for resale shall not be included in the computation of Net Sales hereunder. For purposes of determining Net Sales, the Products shall be deemed to be sold when shipped and a "sale" shall not include reasonable transfers or dispositions as samples or for charitable purposes (including, without limitation, pursuant to an early access, compassionate use, named patient, indigent access or patient assistance program), or transfers or dispositions for preclinical, clinical or regulatory purposes.

1.15 "**Patents**" means (a) pending provisional and non-provisional patent applications, issued patents, utility models and designs; (b) continuations, continued prosecution applications, continuations-in-part, divisions, reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, extensions, renewals, supplementary protection certificates, and term restorations of any of the foregoing and (c) any foreign equivalent or counterpart of any of the foregoing.

1.16 "**Pricing Approval**" means such governmental approval, agreement, determination or decision establishing prices for a Product that can be charged or reimbursed in regulatory jurisdictions where the applicable Governmental Authorities approve or determine the price or reimbursement of diagnostic products.

1.17 "**Product**" means, on a country-by-country basis, synthetic human secretin or any formulation of synthetic human secretin for all diagnostic uses, including without limitation, for use in pancreatic function testing and the visualization of pancreatic duct abnormalities such as (by way of example) (a) stimulation of pancreatic secretions, including bicarbonate to aid in the diagnosis of exocrine pancreas dysfunction, (b) stimulation of gastrin secretion to aid in the diagnosis of gastrinoma; (c) facilitation of identification of the ampulla of Vater and the accessory papilla during endoscopic retrograde cholangiopancreatography (ERCP) and (d) secretin enhanced magnetic resonance cholangiopancreatography (SMRCP). For the avoidance of doubt, any product that was licensed or acquired by Innovate from a Third Party, or discovered by Innovate as part of an independent development program without access to, reliance upon, or use of Repligen Confidential Information, Repligen Know-How, or Assets, in each case as (and to the extent) documented in Innovate's contemporaneous written business records, shall not be considered a Product.

1.18 "**Regulatory Approval**" means all approvals, including Pricing Approvals and government reimbursement approval (in each case if applicable), necessary for the commercial sale of a Product in a given country or regulatory jurisdiction.

1.19 "**Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction.

1.20 "**Regulatory Exclusivity**" means market exclusivity granted by a Governmental Authority designed to prevent the entry of generic product(s) onto the market, including without limitation new chemical entity exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, pediatric exclusivity and 180-day generic product exclusivity, or any equivalent of the foregoing in any country in the world.

1.21 "**Regulatory Materials**" means regulatory applications, submissions, notifications, communications, correspondence, registrations, Regulatory Approvals or other filings made to, received from or otherwise conducted with a Regulatory Authority in order to develop, manufacture, market, sell or otherwise commercialize a Product in a particular country or jurisdiction, specifically including the filings made with FDA and listed on Exhibit A.

1.22 "**Repligen Know-How**" means all Information or other materials in Repligen's possession or Control, as of the Effective Date: (a) relating to synthetic human secretin, or the manufacture or use thereof; or (b) that is necessary for the research, development, manufacture or commercialization of products containing synthetic human secretin or any analogs or derivatives thereof.

1.23 "**Third Party**" means any entity other than Repligen or Innovate or an Affiliate of Repligen or Innovate.

1.24 "**U.S.**" means the United States of America.

2. RESERVED.

3. ASSIGNMENT OF TRANSFERRED ASSETS.

3.1 **Assignment of the Assets.** Repligen hereby sells, assigns, transfers, conveys, and delivers to Innovate, and Innovate hereby purchases, accepts, and acquires from Repligen, all of Repligen's right, title and interest in and to the Assets. Repligen shall (i) on or prior to the Effective Date, provide appropriate assistance to Innovate, at Innovate's expense, to enable Innovate to take the actions listed in Appendix A attached hereto (A) to prepare the assignment to Innovate of the Regulatory Filings set forth on Exhibit A, on a form reasonably acceptable to Repligen and appropriate for recording such assignments with the FDA and (B) record such assignment with the FDA on or after the Effective Date, and (ii) within 3 business days of the Effective Date, provide Innovate with a CD, or other electronic mediums, containing the content of the Electronic Files. For a period of one year after the Effective Date, Repligen shall, upon reasonable request by Innovate and at the expense of Innovate, take any or all of the actions listed in Exhibit B attached hereto. Innovate does not assume, shall not take subject to, and shall not be liable for any liabilities or obligations of any kind or nature, whether absolute, contingent, accrued, known or unknown, of Repligen or any Affiliate of Repligen related to the ownership of the Assets prior to the Effective Date; and such liabilities and obligations shall remain the responsibility of Repligen. Furthermore, Repligen shall continue to be responsible for all Third Party agreements and obligations related to the Assets and not assigned to Innovate under this Agreement, and except as set forth in the next sentence, Innovate shall have no responsibility or liability for such agreements and obligations. At Innovate's request and expense, Repligen will take reasonable actions to enforce such Third Party agreements and obligations.

3.2 No Implied Licenses. No right or license under any Information or Patents of Innovate or the Repligen Know-How is granted or shall be granted by implication or estoppel. All such rights or licenses are or shall be granted only as expressly provided in this Agreement.

4. PAYMENTS.

4.1 Upfront Payment. Innovate shall pay to Repligen a non-refundable, non-creditable cash payment of [***] Dollars ($[***]) on the Effective Date.

4.2 Royalty Payments.

(a) For each Product, Innovate shall pay to Repligen non-refundable, non-creditable royalty payments during the applicable Royalty Term, as calculated (i) by multiplying the applicable royalty rate set forth below by the corresponding amount of incremental Net Sales of such Products in the applicable calendar year and (ii) by subsequently making all applicable adjustments in accordance with Section 4.2(c).

Annual Net Sales	Royalty Rate
For that portion of annual Net Sales that is less than $[***]	[***]%
For that portion of annual Net Sales that is equal to or greater than $[***] but less than or equal to $[***]	[***]%
For that portion of annual Net Sales that is greater than $[***]	[***]%

(b) Royalty Term. Royalties shall be paid under this Section 4.2, on a country-by-country and Product-by-Product basis, during the period of time beginning from the First Commercial Sale of such Product in such country until the later of: (i) the expiration of Regulatory Exclusivity for such Product in such country or (ii) the expiration of the period of ten years following the First Commercial Sale of such Product in any country (the "**Royalty Term**").

(c) Royalty Adjustments. To the extent applicable, Innovate may apply the following adjustments to the royalty payments due to Repligen under this Section 4.2(c).

(i) Third Party Intellectual Property. If Innovate, in its reasonable judgment, is required to obtain a license from any Third Party under any intellectual property owned or controlled by such Third Party that would be infringed or misappropriated by the importation, sale, manufacture or use of a Product, then, the royalty payment that would otherwise be due pursuant to this Section 4.2 shall be reduced by [***] percent ([***]%) of the amount of the royalty payments made by Innovate to such Third Party; provided, however, that the royalty payment that would otherwise be due pursuant to this Section 4.2 with respect to a particular calendar year shall not be reduced by more than [***] percent ([***]%) by operation of this Section 4.2(c)(i).

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

(ii) Generic Competition. For each calendar year during the Royalty Term when Generic Competition exists in the United States, Innovate may reduce the royalty rates to the following amounts if (a) the annual unit sales during such calendar year of the Product in the United States is reduced, due to the entry of generic competition as demonstrated by Innovate to Repligen's reasonable satisfaction, by at least [***]% from the highest annual unit sales in all preceding calendar years in the United States commencing in the calendar year of the First Commercial Sale of such Product and (b) to the extent Innovate has regulatory right under applicable Law to enforce against Generic Competition entry in the United States, demonstrates that it has taken reasonable steps to enforce.

Annual Net Sales	Royalty Rate
For that portion of annual Net Sales that is less than $[***]	[***]%
For that portion of annual Net Sales that is equal to or greater than $[***] but less than or equal to $[***]	[***]%
For that portion of annual Net Sales that is greater than $[***]	[***]%

4.3 Royalty Reports and Payments. Within thirty (30) days following the end of each calendar quarter, commencing with the calendar quarter in which the First Commercial Sale of any Product occurs, Innovate shall provide Repligen with a report containing the following information for the applicable calendar quarter, on a country-by-country and Product-by-Product basis: (i) the amount of gross sales of Product, (ii) the calculation of Net Sales, and (iii) the calculation of the royalty payment due. Concurrent with the delivery of the applicable quarterly report, Innovate shall pay in Dollars all amounts due to Repligen pursuant to Section 4.2 with respect to Net Sales by Innovate, its Affiliates and their respective sublicensees for such calendar quarter.

4.4 Payment Method. All payments due to Repligen hereunder shall be made in Dollars by wire transfer of immediately available funds into an account designated by Repligen.

4.5 Records; Audits. Innovate and its Affiliates and sublicensees will maintain complete and accurate records in sufficient detail to permit Repligen to confirm the accuracy of the calculation of royalty payments and the achievement of milestone events. Upon reasonable prior notice, such records shall be available during regular business hours for a period of three (3) years from the end of the calendar year to which they pertain for examination, and not more often than once each calendar year, by an independent certified public accountant selected by Repligen and reasonably acceptable to Innovate, for the sole purpose of verifying the accuracy of the previously unaudited financial reports furnished by Innovate pursuant to this Agreement. Any such auditor shall not disclose Innovate's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by Innovate or the amount of payments due by Innovate to Repligen under this Agreement. Any amounts shown to be owed but unpaid shall be paid within thirty (30) days from the accountant's report. Repligen shall bear the full cost of such audit unless such audit discloses an underpayment by Innovate of more than [***] percent ([***]%) of the amount due, in which case Innovate shall bear the reasonable cost of such audit.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

4.6 Taxes.

(a) Taxes on Income. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the efforts of the Parties under this Agreement.

(b) Tax Cooperation. The Parties agree to cooperate with one another and use reasonable efforts to reduce or eliminate tax withholding or similar obligations in respect of royalties, and other payments made by Innovate to Repligen under this Agreement. To the extent Innovate is required to deduct and withhold taxes on any payment to Repligen, Innovate shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Repligen an official tax certificate or other evidence of such withholding sufficient to enable Repligen to claim such payment of taxes. Repligen shall provide Innovate any tax forms that may be reasonably necessary in order for Innovate not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by applicable Laws, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax.

5. REPRESENTATIONS AND WARRANTIES.

5.1 Each Party hereby represents and warrants to the other Party as of the Effective Date as follows:

(a) It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement;

(b) It has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (ii) it has taken all necessary corporate action on its part required to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder; and (iii) the Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms;

(c) It is not a party to any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under the Agreement; and

(d) It has not retained any finder, broker, investment banker or the like with respect to the transactions contemplated by this Agreement.

5.2 Repligen hereby represents, warrants and covenants that, as of the Effective Date:

(a) It has sufficient legal or beneficial title, ownership or license, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreements, encumbrances, charges or claims of any kind, of the Assets to grant the assignments to Innovate as purported to be granted pursuant to this Agreement. It is the sole owner of all right, title and interest in and to (free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreements, encumbrances, charges or claims of any kind) Regulatory Filings listed on Exhibit A and the data specified therein and of the other Assets. [***].

(b) It has not received any written notice from any Third Party asserting or alleging that any research or development of the Products by Repligen prior to the Effective Date infringed or misappropriated the intellectual property rights (including any trade secrets) of such Third Party. No part of the Assets was obtained in violation of any contractual or fiduciary obligation owed by Repligen or its employees or agents to any Third Party.

(c) To Repligen's knowledge, the research, development, manufacture and use prior to the Effective Date of Products by or on behalf of Repligen has been carried out, without infringing any published patent applications (evaluating such patent applications as though they were issued with the claims as published as of the Effective Date) or issued patents owned or Controlled by a Third Party.

(d) There are no pending, and to Repligen's knowledge no threatened, adverse actions, suits or proceedings against Repligen involving (i) the Assets or (ii) the research, development, manufacture and use of the Products prior to the Effective Date.

(e) To Repligen's knowledge, there are no activities by Third Parties that would constitute infringement or misappropriation of the Repligen Know-How.

(f) It has not conveyed or licensed, and will not attempt to convey or license after the Effective Date, to a Third Party any right, title, or interest in, to or under any of the Regulatory Filings set forth on Exhibit A or Repligen Know-How which conflicts with any rights granted to Innovate under this Agreement.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

(g) To Repligen's knowledge, no person, other than former or current employees of Repligen who are obligated in writing to assign his/her inventions to Repligen, is an inventor of any of the inventions constituting part of the Assets.

(h) The development of Products has been conducted prior to the Effective Date by Repligen and its Affiliates and, to the knowledge of Repligen, its independent contractors, in compliance in all material respects with all applicable Laws, including all public health, environmental, and safety provisions thereof.

(i) It has disclosed to Innovate all material information known to Repligen with respect to the safety and efficacy of Products as determined from nonclinical or clinical studies.

(j) There are no Patents Controlled by Repligen or its Affiliates that relate to Repligen's synthetic human secretin program and there are no inventions described in an invention disclosure form or draft patent application relating to synthetic human secretin in Repligen's or its Affiliates' Control.

6. DILIGENCE.

6.1 Innovate Diligence Obligations. Innovate shall, directly or indirectly through one or more sublicensees or assignees, use Commercially Reasonable Efforts to commercialize at least one Product. Innovate shall provide written annual reports within 30 days of each anniversary of the Effective Date to Repligen detailing progress made with Products during such preceding annual period including progress on research and development, status of applications for regulatory approvals, manufacturing, sublicensing or assignment, marketing and FDA minutes. Repligen shall have a period of forty five days from receipt of any such report to ask questions or raise any objections to the matters set forth in the report. In the event Repligen does not provide written notice of objection within such period, Repligen shall irrevocably waive its right to claim that Innovate is in breach of its obligation to use Commercially Reasonable Efforts during the period covered by, and with respect to matters set forth in, the report. Moreover, Innovate will provide Repligen an annual plan for its research, development and commercialization activities for the upcoming period of up to 12 months. If Repligen does not provide written notice of objection within 45 days of receipt of such plan, Repligen shall be deemed to have accepted the plan and shall have no right to claim that Innovate is in breach of its obligation to use Commercially Reasonable Efforts during the period covered by, and with respect to matters set forth in, the plan if Innovate substantially executes the plan as presented. For clarity, Innovate shall have no obligation to commercialize more than one Product. Innovate's obligations under this Section 6.1 shall terminate upon the tenth (10^{th}) anniversary of the Effective Date.

6.2 Impact of Failed Diligence. If Innovate provides notice pursuant to the final sentence of Section 6.1 or is in breach of Section 6.1 prior to the completion of the first phase III or other registrational clinical trial involving the use of the Product and fails to cure such breach within ninety (90) days of written notice by Repligen detailing the nature of such breach, then: [***]. For clarity, in lieu of the foregoing, Repligen will have the option to pursue claims under Section 7 for an alleged breach by Innovate of its obligations under this Section 6.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

7. INDEMNIFICATION.

7.1 Indemnification by Repligen. Repligen shall defend, indemnify, and hold Innovate and its Affiliates and their respective officers, directors, employees, and agents (the "**Innovate Indemnitees**") harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such Innovate Indemnitees; provided however, that the aggregate amount payable by Repligen in all instances under this Section 7.1 shall not exceed the sum of [***] (collectively, "**Innovate Damages**"), all to the extent resulting from any claims, suits, proceedings or causes of action brought by such Third Party against such Innovate Indemnitee (collectively, "**Innovate Claims**") that arise from or are based on: (a) a breach of any of Repligen's representations, warranties and obligations under this Agreement; or (b) the willful misconduct or negligent acts of Repligen, its Affiliates, or the officers, directors, employees, or agents of Repligen or its Affiliates. The foregoing indemnity obligation shall not apply to the extent that (i) the Innovate Indemnitees fail to comply with the indemnification procedures set forth in Section 7.4 and Repligen's defense of the Innovate Claims is prejudiced by such failure, or (ii) any of the Innovate Claims arises from, is based on, or results from any activity set forth in Section 7.2(a), 7.2(b) or 7.2(c) for which Innovate is obligated to indemnify the Repligen Indemnitees under Section 7.2.

7.2 Indemnification by Innovate. Innovate shall defend, indemnify, and hold Repligen and its Affiliates and their respective officers, directors, employees, and agents (the "**Repligen Indemnitees**") harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and costs of litigation incurred by such Repligen Indemnitees (collectively, "**Repligen Damages**"), all to the extent resulting from any claims, suits, proceedings or causes of action brought by such Third Party against such Repligen Indemnitee (collectively, "**Repligen Claims**") that arise from or are based on: (a) the research, development, manufacture, or commercialization of Products by or on behalf of Innovate or its Affiliates or its or their licensees, or (b) a breach by Innovate of any of its representations, warranties and obligations under this Agreement, or (c) the willful misconduct or negligent acts of Innovate, its Affiliates, or the officers, directors, employees, or agents of Innovate or its Affiliates. The foregoing indemnity obligation shall not apply to the extent that (i) the Repligen Indemnitees fail to comply with the indemnification procedures set forth in Section 7.4 and Innovate's defense of the Repligen Claims is prejudiced by such failure, or (ii) any of the Repligen Claims arises from, is based on, or results from any activity set forth in Section 7.1(a) or 7.1(b) for which Repligen is obligated to indemnify the Innovate Indemnitees under Section 7.1.

7.3 Indemnification for Product Liability Claims. Innovate shall defend, indemnify, and hold the Repligen Indemnitees harmless from and against any and all Repligen Damages, all to the extent resulting from Repligen Claims that arise from or are based on: (a) death or injury to person or property as a result of any actual or alleged defect in any Product; (b) inaccurate test results with respect to any patient or reported in any clinical database, which inaccuracies are related to any use or misuse of the Product; (c) any actual or alleged warranty, recall or similar liability for any Product; or (d) any statutory liability of the Repligen Indemnitees or any liability of the Repligen Indemnitees assessed with respect to any failure to warn arising out of any Product.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

7.4 Indemnification Procedures. The Party claiming indemnity under this Article 7 (the "**Indemnified Party**") shall give written notice to the Party from whom indemnity is being sought (the "**Indemnifying Party**") promptly after learning of such Innovate Claims or Repligen Claims (as applicable) (each a "**Claim**"). The Indemnified Party shall provide the Indemnifying Party with reasonable assistance, at the Indemnifying Party's expense, in connection with the defense of the Claim for which indemnity is being sought. The Indemnified Party may participate in and monitor such defense with counsel of its own choosing at its sole expense; provided, however, the Indemnifying Party shall have the right to assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not settle any Claim without the prior written consent of the Indemnified Party, not to be unreasonably withheld, unless the settlement involves only the payment of money. So long as the Indemnifying Party is actively defending the Claim in good faith, the Indemnified Party shall not settle or compromise any such Claim without the prior written consent of the Indemnifying Party. If the Indemnifying Party does not assume and conduct the defense of the Claim as provided above, (a) the Indemnified Party may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnified Party may deem reasonably appropriate (and the Indemnified Party need not consult with, or obtain any consent from, the Indemnifying Party in connection therewith), and (b) the Indemnifying Party shall remain responsible to indemnify the Indemnified Party as provided in this Article 7.

7.5 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES OR LOSS OF PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 7.5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 7.1 OR 7.2 OR THE DAMAGES AND REMEDIES AVAILABLE WITH RESPECT TO MATTERS COVERED BY SECTIONS 4.5, 6.2 AND 12.13.

7.6 Exclusive Remedies. Each of the Parties hereto acknowledges and agrees that following the Effective Date, except with respect to matters covered by Sections 4.5, 6.2 and 12.13, the indemnification provisions of Section 7 shall be the sole and exclusive remedies of the parties hereto. The provisions of this Section 7.6 will not prevent or limit a cause of action (i) under Section 12.13 to obtain an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions hereof, (ii) under Section 6.2 to enforce, or seek damages for a breach of, Innovate's obligations under Section 6.1, and (iii) under Section 4.5 to enforce any decision or determination of the independent certified public accountant.

7.7 Insurance.

(a) Innovate shall procure and maintain insurance adequate to cover its activities with respect to the Assets and the Products consistent with normal business practices of prudent companies similarly situated at all times during which any Product is being clinically tested in human subjects or commercially distributed or sold by or on behalf of Innovate. Without limiting the foregoing, such insurance policies following any Regulatory Approval of the Product shall include aggregate coverage amounts as provided on Exhibit C attached hereto and shall name Repligen as an additional insured party. If such insurance is written on a claims-made form, it shall continue for [***] ([***]) years following termination of this Agreement. During (i) the term of this Agreement and (ii) in the case of insurance written on a claims-made form, [***] ([***]) years following termination of this Agreement, Innovate shall not permit such insurance to be reduced, expired, materially amended or canceled during the period of such insurance. It is understood that such insurance shall not be construed to create a limit of Innovate's liability with respect to its indemnification obligations under this Article 7. Innovate shall provide Repligen with written evidence of such insurance upon request. The insurance shall be valid in any location worldwide regarding the activities performed by each of Innovate and Repligen hereunder (including worldwide jurisdictions) for any destination or lawsuit.

(b) If Innovate is in breach of Section 7.7(a) and fails to cure such breach within ninety (90) days of written notice by Repligen detailing the nature of such breach, then: Repligen will have the option to require Innovate to sell, assign, transfer, convey, and deliver to Repligen, for $[***] in cash, all of the Assets, the Products and all materials related thereto then controlled by Innovate or its Affiliates, and all data generated by or on behalf of Innovate in connection with the development of Products as defined under Section 1.15 and all Regulatory Approvals and applications for Regulatory Approval of Products as defined under Section 1.15. Any such transfer pursuant to Repligen's exercise of such option shall be at Innovate's cost and be completed within thirty (30) days of Repligen's written notice to Innovate that it has exercised such option.

(c) Innovate shall use Commercially Reasonable Efforts that such insurance shall contain an explicit clause, stating that Innovate and its insurer waive their rights of subrogation against Repligen and its directors, employees and/or any one on its behalf with respect to the insurance. The insurance shall be primary to any other insurance maintained by each of Innovate and Repligen and each Party hereby waives any claim or demand as to participation in any such other insurance.

(d) Prior to Innovate commencing any clinical trial involving the use of the Product, Innovate shall pay to Repligen cash payments in amounts equal to the amounts Repligen will reasonably be required to pay to increase the aggregate coverage amount of Repligen's insurance covering the Product from [***] Dollars ($[***]) per year to $[***] per year (the "**Increased Coverage Amount**").

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

(e) On the earlier of (i) the third anniversary of the Effective Date and (ii) prior to the First Commercial Sale, Innovate shall pay to Repligen a one-time cash payment in an amount equal to the amount Repligen will reasonably be required to pay to procure and maintain supplemental extended runoff insurance in an aggregate coverage amount of $[***] covering the Product (the "**Runoff Policy**"). From and after the date on which Innovate pays such amount for Repligen to procure the Runoff Policy, Repligen will be responsible for any and all annual premium amounts necessary to maintain the Increased Coverage Amount.

8. INTELLECTUAL PROPERTY.

8.1 Patent Prosecution. Innovate shall have the sole right to file, prosecute, and maintain any Patents related to a Product and shall use Commercially Reasonable Efforts to do so in order to support the development and commercialization of Products.

8.2 Trademarks. Innovate shall have the right to brand the Products using the name SecreFlo, Innovate-related trademarks and any other trademarks and trade names it determines appropriate for the Products, which may vary by country or within a country ("**Product Marks**"); provided that Innovate shall not, and shall ensure that its Affiliates and licensees will not, make any use of the trademarks or house marks of Repligen (including Repligen's corporate name) or any trademark confusingly similar thereto. Innovate shall own all rights in the Product Marks and shall register and maintain, at its own cost and expense, the Product Marks in the countries and regions that it determines reasonably necessary.

9. TREATMENT OF CONFIDENTIAL INFORMATION.

For purposes of this Agreement, "**Confidential Information**" shall mean all non-public scientific, technical, financial or business information which is disclosed by or on behalf of either Party hereunder to the other Party hereunder before, on, or after the Effective Date, whether in writing, or by oral or visual disclosure or presentation, and which is treated by the disclosing Party as confidential or proprietary; provided, that from and after the Effective Date, all Repligen Know-How is deemed to be Confidential Information of Innovate unless and until Repligen exercises its reversionary right set forth in Section 6.2(a). Notwithstanding the foregoing, "Confidential Information" shall not include information that the receiving Party can demonstrate by competent evidence:

(a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the disclosing Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) is independently discovered or developed by the receiving Party without the use of Confidential Information of the disclosing Party; or

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[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

(e) is disclosed to the receiving Party, on a non-confidential basis, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others.

Notwithstanding the foregoing, the receiving Party shall not be prohibited from disclosing the disclosing Party's Confidential Information to the extent such information is required to be disclosed by court order or by applicable Law or government regulation; provided, however, that in such event, the receiving Party shall give reasonable advance notice (except where impracticable) to the disclosing Party of such required disclosure and, at the disclosing Party's request and expense, shall cooperate with the disclosing Party's efforts to contest such disclosure, and/or to obtain a protective order or other confidential treatment of the Confidential Information required to be disclosed.

The receiving Party agrees that it will hold Confidential Information received from the disclosing Party in secrecy and confidence and will not disclose it to any Third Party, or use it for any purpose, other than for the purpose of the performance of this Agreement. The receiving Party further agrees that it will restrict disclosure of Confidential Information within its own organization and Affiliates to those persons having a need to know it for the purpose of this Agreement, and that such persons will be advised of the obligation set forth in this Agreement and obligated in like fashion. If the receiving Party learns of any disclosure by it or its employees, agents, independent contractors, or Affiliates of any Confidential Information of the disclosing Party not in accordance with this Section 9, the receiving Party shall promptly notify the disclosing Party of such unauthorized disclosure.

The above obligations of the receiving Party with respect to its treatment of Confidential Information shall commence as of the Effective Date and continue for a period of [***] ([***]) years following disclosure of such Confidential Information. This Agreement shall not be construed as granting any license rights with respect to the Confidential Information. Except as otherwise required by applicable Laws and regulations or rules of any securities exchange, the Parties hereby agree that any disclosure of the terms and conditions of this Agreement shall be subject to the other Party's prior written agreement; provided, however, that each Party may disclose the terms and conditions of this Agreement to a prospective or actual investor or lender, acquirer, licensee or collaborator pursuant to a written confidentiality agreement of the same or more restrictive provisions as those contained herein, and provided further that if any such disclosure is required by laws, regulations or rules of a securities exchange, the Party required to make such disclosure shall notify the other Party of any such disclosure and shall seek confidential treatment of portions of this Agreement where reasonably available.

10. NOTICES.

10.1 All notices and statements to either Party required under this Agreement shall be made in writing delivered via certified mail, return receipt requested, courier, provided that evidence of delivery is made, or facsimile with confirmation of such transmission addressed to such Party at the following addresses or faxed to the appropriate numbers set forth below (with the copies to other Parties set forth below) or to such other address as may be designated from time to time:

To Repligen:
Repligen Corporation
41 Seyon Street
Building 1, Suite 100
Waltham, MA 02453
Attn: President
Fax: (781) 250-0115

With a copy to:
Goodwin Procter LLP
Exchange Place

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

Boston, MA 02109
Attn: Arthur R. McGivern
Fax: 617-523-1231

To Innovate:
Innovate Biopharmaceuticals Inc.
8601 Six Forks Road, Suite 400
Raleigh, NC 27615
Attn: President

With a copy to:
Hutchison PLLC
3110 Edwards Mill Road, Suite 300
Raleigh, NC 27612
Attn: William N. Wofford, Esq.
Fax: (866) 479-7550

10.2 All notices and statements provided to a Party hereunder shall be deemed to have been given as of the date received, or at the time of delivery of a facsimile to the relevant facsimile number above.

10.3 Each Party hereto may change its address and contact information set forth above for the purpose of this Agreement by providing written notice to the other Party of the same from time to time.

11. DISPUTE RESOLUTION

11.1 **Executive Officers.** Unless otherwise set forth in this Agreement, in the event of a dispute arising under this Agreement between the Parties, the Parties shall refer such dispute to the respective Executive Officers, and such Executive Officers shall attempt in good faith to resolve such dispute. Either Party may initiate such informal dispute resolution by sending written notice of the dispute to the other Party, and, within twenty (20) days after such notice, such Executive Officers shall meet for attempted resolution by good faith negotiations. If such Executive Officers are unable to resolve such dispute within thirty (30) days of their first meeting for such negotiations, either Party may seek to have such dispute resolved in accordance with the following Sections 11.2 and 11.3.

11.2 **Governing Law.** This Agreement shall be governed and interpreted in accordance with the laws of the State of Delaware, without regard to conflict of law provisions.

11.3 Jurisdiction; Venue. Any dispute arising under this Agreement, or other legal proceeding relating to this Agreement or the enforcement of any provision of this Agreement must be brought or otherwise commenced solely and exclusively in courts of competent jurisdiction located in the city of Wilmington, Delaware. Consistent with the preceding sentence, each of the Parties: (a) expressly and irrevocably consents and submits to the jurisdiction of the courts of competent jurisdiction in the city of Wilmington, Delaware (and each appellate court located in the State of Delaware) in connection with any such legal proceeding; (b) expressly agrees that the courts of competent jurisdiction in the city of Wilmington, Delaware shall be deemed to be a convenient forum; and (c) expressly agrees not to assert (by way of motion, as a defense or otherwise), in any such legal proceeding commenced in the courts of competent jurisdiction in the city of Wilmington, Delaware, any claim that such Party is not subject personally to the jurisdiction of such court, that such legal proceeding has been brought in an inconvenient forum, that the venue of such proceeding is improper or that this Agreement or the subject matter of this Agreement may not be enforced in or by such court.

12. MISCELLANEOUS.

12.1 Acknowledgement. Each Party acknowledges that it has negotiated and entered into this Agreement in good faith.

12.2 Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, it shall be modified, if possible, to the minimum extent necessary to make it valid and enforceable or, if such modification is not possible, it shall be stricken and the remaining provisions shall remain in full force and effect.

12.3 Interpretation.

(a) The English language of this Agreement shall govern any interpretation of or dispute regarding this Agreement.

(b) Any reference in this Agreement to a Section or Exhibit is a reference to the Sections and Exhibits of this Agreement unless the context requires otherwise. Any reference to a Section shall be deemed to include a reference to any subsidiary Sections.

(c) The captions of the Sections are included for reference purposes only and are not intended to be a part of the Agreement or in any way to define, limit or describe the scope or intent of the particular provision to which they refer.

(d) Whenever the context requires: the singular number shall include the plural and vice versa; the masculine gender shall include the feminine and neuter gender; the feminine gender shall include the masculine and neuter gender; and the neuter gender shall include the feminine and masculine gender.

(e) The Parties agree that any rule of construction to the effect that ambiguities are to be resolved against the drafting party shall not be applied in the construction or interpretation of this Agreement.

(f) As used in this agreement “include” and “including” and variations thereof shall not be deemed to be terms of limitation, but rather shall be deemed to be followed by the words “without limitation.”

12.4 Assignment. This Agreement shall not be assigned by either Party, without the prior written consent of the other Party; provided that either Party may assign this Agreement without such consent: (i) to an Affiliate; (ii) in the event of a merger, consolidation or similar reorganization with or into a Third Party, whether by acquisition, merger, sale of stock, change of control or otherwise, or (iii) in the event of a sale of all or substantially all of the assets to which this Agreement relates, this Agreement shall be assigned to or become the obligation and liability of the acquiring entity. Any purported assignment in violation of this Section 12.4 shall be void.

12.5 Expenses. Innovate shall reimburse Repligen for its documented out of pocket legal fees incurred in connection with negotiating and consummating the transactions contemplated by this Agreement in an amount not to exceed $[***], subject to Innovate's review of all invoices for such fees, which shall be provided to Innovate by Repligen within 45 days of the Effective Date or the incurrence of such fees by Repligen, and provided that all such fees shall be reasonable and customary for transactions of the type contemplated by this Agreement. Except as otherwise expressly provided herein, all parties will be responsible for their own costs and expenses, including counsel fees, incurred in connection with the transactions contemplated by this Agreement.

12.6 Force Majeure. If the performance of this Agreement or any obligation hereunder (except for the payment of money) is prevented, restricted or interfered with by reason of fire or other casualty or accident, strikes or labor disputes, inability to procure raw materials, power or supplies, war, invasion, civil commotion or other violence, compliance with any order of any governmental authorities or any other act or conditions whatsoever beyond the reasonable control of either Party hereto, the Party so affected upon giving a prompt notice to the other Party shall be excused from such performance to the extent of such prevention, restriction or interference; provided, however, that the Party so affected shall use commercially reasonable efforts to avoid or remove such causes of non-performance and shall continue performance hereunder with the utmost dispatch whenever such causes are removed, to the extent commercially reasonable.

12.7 Entirety of Agreement. This Agreement contains the entire understanding of the Parties hereto with respect to the subject matter contained herein. Without limiting the generality of the foregoing, that certain letter of intent between the Parties executed on or about August 12, 2014 shall be of no further force and effect. There are no restrictions, promises, covenants or understandings other than those expressly set forth herein, and no rights or duties on the part of either Party are to be implied or inferred beyond those expressly herein provided for. The Parties may, from time to time during the term of this Agreement, amend, modify, vary, waive or alter any of the provisions of this Agreement, but only by a written instrument that makes specific reference to this Agreement which is duly executed by each Party, or in the case of waiver, by the Party or Parties waiving compliance.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

12.8 Further Assurances; Personnel. Each Party agrees to duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including, without limitation, the filing of such additional assignments, agreements, documents and instruments, that may be necessary or as the other Party hereto may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement. Repligen acknowledges that Innovate may elect to engage one or more former Repligen employees or consultants as employees or consultants to assist with the development and commercialization of Products and Repligen hereby consents to such engagement and waives any covenants regarding confidentiality, solicitation or competition that it may have against or otherwise with respect to such persons, solely to the extent deemed necessary or helpful by Innovate to develop and commercialize Products.

12.9 No Partnership. For the purposes of this Agreement and all obligations to be performed hereunder, each Party shall be, and shall be deemed to be, an independent contractor and not an agent, partner, joint venturer or employee of the other Party. Neither Party shall have authority to make any statements, representations or commitments of any kind, or to take any action which shall be binding on the other Party, except as may be explicitly provided for herein or authorized in writing.

12.10 Use of Other Party's Name. Neither Party shall use the name, trademark, trade name or logo of the other Party or their respective employee(s) in any publicity, promotion, press release or disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party, except as may be required by applicable Laws or regulations.

12.11 Waiver. The waiver by either Party of any breach, default or omission in the performance or observance of any of the terms of this Agreement by the other Party shall not be deemed to be a waiver of any other such breach, default or omission. Any waiver of this Agreement must be in writing and signed by the waiving Party to be effective.

12.12 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, and all of such counterparts taken together shall constitute one and the same instrument. Counterparts may be signed and delivered by facsimile, each of which shall be binding when sent.

12.13 Specific Performance. The Parties hereto acknowledge and agree that the Parties hereto would be irreparably damaged if any of the provisions of this Agreement are not performed in accordance with their specific terms or are otherwise breached and that any nonperformance or breach of this Agreement by any Party hereto could not be adequately compensated by monetary damages alone and that the Parties hereto would not have any adequate remedy at law. Accordingly, such Party shall be entitled to enforce any provision of this Agreement by a decree of specific performance and temporary, preliminary and permanent injunctive relief to prevent breaches or threatened breaches of any of the provisions of this Agreement without posting any bond or other undertakings.

[SIGNATURE PAGE FOLLOWS]

In Witness Whereof, the parties hereto, intending to be legally bound hereby, have duly executed this Asset Purchase Agreement to be effective as of the Effective Date.

Innovate Biopharmaceuticals Inc.		**Repligen Corporation**	
By:	/s/ Jay P. Madan	By:	/s/ Howard Benjamin
Name:	Jay P. Madan	Name:	/s/ Howard Benjamin
Title:	President	Title:	VP BD

EXHIBIT A

Regulatory Filings

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

EXHIBIT B

1. Reasonable access to the Physical Files during normal business hours at mutually agreeable times, and at such time that Repligen is no longer required to maintain the Physical Files on premise under applicable Law, whether such time is within one year of the Effective Date or thereafter, enable Innovate, at Innovate's expense, to transfer the Physical Files from Repligen's premise to Innovate's designated location.

2. Provide the appropriate release under any applicable contracts between Repligen and a Third Party to enable Innovate to discuss with such Third Party matters pertaining to the research, development, manufacture or commercialization of the Products

CONFIDENTIAL TREATMENT REQUESTED

EXHIBIT C

Insurance Requirements

1. Prior to the commencement of clinical work using the Product, Innovate shall maintain product liability insurance in the aggregate amount of $[***] per year ($[***] per occurrence).

2. Upon the commencement of the first clinical trial using the Product, Innovate shall increase its product liability insurance to an aggregate amount of $[***] per year ($[***] per occurrence).

3. Prior to the First Commercial Sale, Innovate shall increase its product liability insurance to an aggregate amount of $[***] per year ($[***] per occurrence).

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

Appendix A

Critical Path Activities

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

Exhibit 10.4

APAZA

LICENSE AGREEMENT

between

SEACHAID PHARMACEUTICALS, INC.

and

GI THERAPEUTICS, INC.

Dated as of April 19, 2013

APAZA
LICENSE AGREEMENT

This License Agreement (the "Agreement") is entered into this 19th day of April, 2013 (the "Effective Date"), by and among Seachaid Pharmaceuticals, Inc., a Delaware corporation ("Licensor"), and GI Therapeutics, Inc., a North Carolina corporation ("Licensee"). Licensee and Licensor may each be referred to in this Agreement individual as a "Party" and collectively as the "Parties."

BACKGROUND

A. Biocon Limited ("Biocon") acquired certain patent rights, know-how and other intellectual property with respect to the compound known as Apaza from Nobex Corporation ("Nobex") pursuant to an Asset Purchase Agreement dated December 1, 2005.

B. Biocon licensed such patent rights, know-how and other intellectual property to Licensor pursuant to that certain License Agreement dated as of July 29, 2008 (the "Biocon License Agreement").

C. Licensee desires to obtain, with respect to the Territory, an exclusive license under patent rights and intellectual property controlled by Licensor with respect to Apaza, and Licensor is willing to grant, with respect to the Territory, an exclusive license to Licensee under such patent rights and other intellectual property with respect to Apaza, all as more particularly described in, and subject to, the terms and conditions set forth in this Agreement.

AGREEMENT

NOW THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS

1.1 "Affiliate(s)" means, with respect to a Person, another Person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, such Person. For the purposes of this definition only, "control" means, with respect to a Person, the ownership by another Person of greater than 50% of the income or voting interests of such Person or such other arrangement as constitutes the direct or indirect ability to direct the management, affairs or actions of such Person.

1.2 "Agreement" has the meaning set forth in the opening paragraph.

1.3 "Apaza Compound" means a compound that is (i) the molecule known as "Apaza" comprised of 4-APAA linked to 5-ASA, or (ii) a compound that is a derivative, analog, fragment or metabolite or a combination thereof, including, without limitation, the compounds generically or specifically described in the Licensed Patents, alone or in combination with other molecules, provided that the compound is a primary active moiety in such combination.

1.4 "Apaza Know-How" means Know-How used in connection with or related to the Apaza Compounds or Licensed Products that Licensor or any of its Affiliates Controls as of the Effective Date and includes, without limitation, the information identified on Exhibit B.

1.5 "Bankruptcy Code" has the meaning set forth in Section 14.16.

1.6 "Biocon" has the meaning set forth in Recital A.

1.7 "Biocon License Agreement" has the meaning set forth in Recital B.

1.8 "Commercialization" or "Commercialize" means the commercial-scale manufacturing, obtaining pricing and reimbursement approvals, marketing, promoting, distributing, importing, exporting, offering for sale or selling a human pharmaceutical product.

1.9 "Competing Business" means the Development or Commercialization of a product in the Territory that [***].

1.10 "Confidential Information" means all trade secrets, processes, formulae, data, know-how, improvements, inventions, chemical or biological materials, chemical structures, techniques, marketing plans, strategies, or other information that has been created, discovered, or developed by a Party, or has otherwise become known to a Party, or to which rights have been assigned to a Party, as well as any other information and materials that are deemed confidential or proprietary to or by a Party (including, without limitation, all information and materials of a Party's customers and any other Third Party and their consultants), in each case that are disclosed by such Party to the other Party, regardless of whether any of the foregoing are marked "confidential" or "proprietary" or communicated to the other by the disclosing Party in oral, written, graphic, or electronic form.

1.11 "Control" or "Controlled" means with respect to any (a) item of information, including, without limitation, Know-How, or (b) intellectual property right, the possession (whether by ownership or license, other than pursuant to this Agreement) by a Party of the right to grant to the other Party access and/or a license on the terms and conditions provided in this Agreement under such item or right without violating the terms of any agreement or other arrangements with any Third Party (including any Regulatory Authority or Governmental Entity) existing before the Effective Date.

1.12 "Development" means pre-clinical and clinical drug development activities reasonably related to the discovery and development of pharmaceutical compounds and submission of information to a Regulatory Authority, including, without limitation, toxicology, pharmacology and other discovery and pre-clinical efforts, test method development and stability testing, manufacturing process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical studies (including, without limitation, pre- and post-approval studies) and activities relating to obtaining Regulatory Approval but excluding other Commercialization activities. When used as a verb "Develop" means to engage in Development.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

1.13 "Disclosing Party" has the meaning set forth in Section 12.1

1.14 "Effective Date" has the meaning set forth in the opening paragraph.

1.15 "EMEA" means to the European Medicines Agency headquartered in London or any successor agency thereto, responsible for the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

1.16 "European Union" or "EU" means the countries compromising the European Union as it may be constituted from time to time, together with those additional countries included in the European Economic Area as it may be constituted from time to time, and any successors to, or new countries created from, any of the foregoing.

1.17 "Expiration" has the meaning set forth in Section 13.1

1.18 "FDA" means the United States Food and Drug Administration or any successor agency thereto.

1.19 "First Commercial Sale" of each Licensed Product means, on a country-by-country basis, the date of the first arm's length transaction, offering for sale, transfer or disposition for value to a Third Party of a Licensed Product by or on behalf of Licensee or its Affiliates in such country. For purposes of clarity, the use of any Licensed Product in clinical trials, pre-clinical studies or other research, development, manufacturing, or promotion activities or the disposal or transfer of a Licensed Product for a bona fide charitable purpose or for purposes of a commercially reasonable sampling program shall not be deemed to be an arm's length transaction, transfer or disposition for value for purposes of this definition.

1.20 "Force Majeure" has the meaning set forth in Section 14.6

1.21 "GAAP" shall mean the generally accepted accounting principles and accepted practices of the accounting profession in the United States, including without limitation the definitive pronouncements of accounting issued by the Financial Accounting Standards Board.

1.22 "Governmental Entity" means any arbitrator, court, judicial, legislative, administrative or regulatory agency, commission, department, board or bureau or body or other governmental authority or instrumentality or any person or entity exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government, whether foreign, federal, state provincial, local or other (including without limitation any domestic or foreign governmental Regulatory Authority involved in the granting of approvals for the manufacture, sale, reimbursement and/or pricing of a pharmaceutical product such as the FDA).

1.23 "Improvement" means any discovery, invention, improvement or modification (whether or not patentable) which is related to the Licensed Technology or the Licensed Products.

1.24 "IND" means any Investigational New Drug Application, as defined in the United States Food, Drug and Cosmetic Act, filed with the FDA pursuant to Part 312 of Title 21 of the U.S. Code of Federal Regulations, including any amendments thereto. References herein to IND shall include, to the extent applicable, any comparable filing(s) outside the U.S. (such as a CTA in the European Union).

1.25 "Indemnitor" and "Indemnitee" have the meanings given to them in Section 11.4.1

1.26 "Initial Payment" has the meaning set forth in Section 3.1.

1.27 "Joint Improvements" has the meaning set forth in Section 7.3.

1.28 "Know-How" means all non-patented trade secrets, inventions, discoveries, data (including data from scientific and clinical studies and other research), ideas, information, formulation data, specifications, processes, methods, techniques, materials, technology, results, customer lists, vendor and supplier information, marketing studies, market research, business and marketing plans and proposals, information technology, and all other information and know-how, whether or not patentable or protected as a trade secret, including without limitation, biological, chemical, biochemical, toxicological, pharmacological, metabolic, formulation, clinical, analytical and stability information, manufacturing processes, production batch records, standard operating procedures and protocols relating to the research scale, pilot scale and commercial scale synthesis of a compound or product (other than such information and data which is or becomes the subject of a patent or patent application). Know-How includes know-how in the possession of vendors, service providers, former owners and other Third Parties, where such Know-How is Controlled by the relevant Party.

1.29 "Licensed Patents" means all patents owned or Controlled by Licensor claiming rights related to the composition, formulation or use of any Apaza Compound, including without limitation those patents and patent applications listed on Exhibit A including any and all Patent Rights related thereto.

1.30 "Licensed Products" means any products the manufacture, use or sale of which is covered by a Valid Claim of one or more Licensed Patents.

1.31 "Licensed Technology" means the Licensed Patents and the Apaza Know-How.

1.32 "Licensee" has the meaning set forth in the opening paragraph.

1.33 "Licensee Improvements" has the meaning set forth in Section 7.3.

1.34 "Licensor" has the meaning set forth in the opening paragraph.

1.35 "Licensor Improvements" has the meaning set forth in Section 7.3.

1.36 "Lien" means any mortgage, pledge, lien, security interest, charge, claim, encumbrance, or restriction on transfer.

1.37 "Losses" means any and all damages (including all incidental, consequential, statutory and treble damages except as otherwise specifically limited in this Agreement), awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees, liabilities, obligations, taxes, liens, losses, lost profits and expenses (including, without limitation, court costs, interest and reasonable fees of attorneys, accountants and other experts), together with all documented out-of-pocket costs and expenses incurred in complying with any judgments, orders, decrees, stipulations and injunctions.

1.38 "MAA" means a Marketing Authorization Application filed with the EMEA for approval to market and sell a drug product in the European Union.

1.39 "Material Underpayment" has the meaning set forth in Section 5.2.2.

1.40 "NDA" means a New Drug Application filed with the FDA for approval to market and sell a drug product in the United States.

1.41 "Net Sales" means with respect to a Licensed Product, the gross amount invoiced for sales or other transfers of such Licensed Product by Licensee, its Affiliates and all Sublicensees to Third Parties, after deduction of the following and in each case in accordance with GAAP:

(a) normal and customary trade, quantity or cash discounts actually allowed or paid;

(b) refunds, rebates, chargebacks, retroactive price adjustments and service allowances actually allowed or paid;

(c) actual rebates and similar payments made to managed care entities and any Governmental Entity such as, by way of illustration and not in limitation of the Parties' rights hereunder, federal or state Medicaid, Medicare or similar state programs in the United States or equivalent governmental programs in any other country;

(d) amounts actually repaid or credited by reason of rejection, returns or recalls of goods;

(e) actual write-offs and reserves (without duplication) for doubtful accounts;

(f) excise taxes, sales taxes, consumption taxes and other similar taxes, customs duties, customs levies and export and import fees borne on the sale, transfer, use or distribution of such products to Third Parties; and

(g) charges for transportation costs included in the invoiced amount, including shipping, freight, special packaging and related charges, transit insurance charges, distribution expenses, and other costs directly related to the distribution of any such products actually borne by the Licensee, its Affiliates and Sublicensees.

Sales of Licensed Products by and between Licensee and its Affiliates or Sublicensees are not sales to Third Parties and shall be excluded from Net Sales calculations for all purposes, except where the Affiliate or Sublicensee is a retail pharmacy, hospital or similar entity that is in the business of selling the Licensed Products directly to consumers. The obligation to pay royalties to Licensor under this Agreement is imposed only once with respect to the same unit of Licensed Product. A Net Sale shall be deemed to have occurred upon Licensee, it Affiliate or sublicensee's receipt of invoiced amounts.

1.42 "Nobex" has the meaning set forth in Recital A.

1.43 "Non-Royalty Sublicensing Revenue" means, with respect to any Licensed Product, the aggregate upfront cash payments directly received by Licensee and its Affiliates in consideration for the Licensee or its Affiliates entering into a sublicense agreement under the Licensed Technology with a Third Party sublicensee with respect to such Licensed Product in the Territory. For the avoidance of doubt, "Non-Royalty Sublicensing Revenue" shall not include (a) any royalties received by Licensee; (b) development and commercial milestone payments, including without limitation, those set forth in sections 3.2 and 3.3; (c) reasonable amounts received by Licensee or its Affiliates to perform research, development, regulatory, marketing, or manufacturing or other services, (d) amounts received in reimbursement of patent or other out-of-pocket expenses actually incurred, and (e) amounts received in consideration for the purchase of any securities of the Licensee or its Affiliates at fair market value.

1.44 "Party" and "Parties" have the meaning set forth in the opening paragraph.

1.45 "Patent Claims" has the meaning set forth in Section 9.4.

1.46 "Patent Rights" mean:

(a) All patent applications (including provisional patent applications and PCT patent applications) and patents in any country or supranational jurisdiction and all divisions, continuations of these applications, all patents issues from these applications, divisions, and continuations, and any reissues, reexaminations, substitutions, renewals, confirmations, supplementation protection certificates, registrations, revalidations, additions of or to and extensions of all such patents and any other form of government-issued right substantially equivalent to any of the foregoing;

(b) To the extent that the following contain one or more claims directed to the invention(s) disclosed in 1.46(a):

(i) continuations-in-part of 1.46(a);

(ii) all divisions and continuations-in-part;

(iii) all patents issuing from these continuations in part, divisions and continuations;

(iv) priority patent application(s) of 1.46(a); and

(v) any reissues, reexaminations, substitutions, renewals, confirmations, supplementation protection certificates, registrations, revalidations, additions of or to and extensions of these patents;

(c) to the extent that the following contain one or more claims directed to the invention(s) disclosed in 1.46(a): all counterpart foreign and U.S. patent applications and patents to 1.46 (a) and 1.46(b).

1.47 "Payments" has the meaning set forth in Section 5.1.3.

1.48 "Person" means (as the context requires) an individual, a corporation, a partnership, an association, a trust, a limited liability company, or other entity or organization, including Governmental Entity.

1.49 "Phase II Trial" means a human clinical trial of a compound in any country that would satisfy the requirements of 21 C.F.R. 312.21(b) and is intended to explore a variety of doses, dose response, and/or duration of effect, and/or to generate initial evidence of clinical safety and activity in a target patient population or the equivalent Regulatory Filings with similar requirements in a country other than the United States.

1.50 "Phase III Trial" means a human clinical trial of a compound, performed after preliminary evidence of suggesting effectiveness of the compound has been obtained, conducted for inclusion in: (i) that portion of an FDA submission and approval process which provides for the continued trials of a product on sufficient numbers of human patients to confirm with statistical significance the safety and efficacy of a product sufficient to support a Regulatory Approval for the proposed indication, as more fully described in 21 C.F.R. 312.21(c), or (ii) equivalent Regulatory Filings with similar requirements in a country other than the United States.

1.51 "Receiving Party" has the meaning set forth in Section 12.1.

1.52 "Regulatory Approval" means, in relation to any Licensed Product, the registrations, authorizations and approvals of any Regulatory Authority that are required to be obtained prior to the marketing or sale of product in a jurisdiction in the Territory. Neither a tentative approval nor an approvable letter shall be considered "Regulatory Approval."

1.53 "Regulatory Authority" means, with respect to any particular country, the Governmental Entity of such country, with the primary responsibility over the Development and/or Commercialization of the Apaza Compound or a Licensed Product, including such Governmental Entities that have jurisdiction over the pricing of the Licensed Product.

1.54 "Regulatory Filing" means, in relation to any Licensed Product, any filing with a Regulatory Authority relating to or to permit or request, as applicable, the clinical evaluation or Regulatory Approval of a pharmaceutical product. Regulatory Filings include without limitation Investigational New Drug Applications, Clinical Trial Authorizations, MAAs and NDAs.

1.55 "Remedies" has the meaning set forth in Section 9.2.

1.56 "Royalty Term" has the meaning set forth in Section 4.3.

1.57 "Sublicensee" means a Third Party to whom Licensee has granted rights under Section 2.

1.58 "Sublicensing Proceeds" has the meaning set forth in Section 4.2.

1.59 "Tax" or "Taxes" means all taxes, fees, levies, duties, tariffs, imposts, and governmental impositions or charges of any kind in the nature of (or similar to) taxes, payable to any federal, state, local or foreign taxing authority, whether disputed or not, including (without limitation) (i) income, franchise, profits, gross receipts, ad valorem, net worth, value added, sales, use, service, real or personal property, special assessments, capital stock, license, payroll, withholding, employment, social security (or similar), workers' compensation, unemployment compensation, disability, utility, severance, productions, excise, stamp, occupation, premiums, windfall profits, environmental, customs duties, registration, alternative and add on minimum, estimated, transfer and gains taxes, or other tax of any kind whatsoever and (ii) in all cases, including interest, penalties, additional taxes and additions to tax imposed with respect thereto.

1.60 "Territory" means the United States, Canada, Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom of Great Britain and Northern Ireland.

1.61 "Third Part(y/ies)" means any person(s) or entit(y/ies) other than Licensee, Licensor, or their respective Affiliates.

1.62 "Third Party Claims" have the meaning set forth in Section 11.4.2.

1.63 "Valid Claim" means, with respect to a Licensed Patent, any claim from (a) an issued and unexpired or issued and extended patent in the Territory that has not lapsed, been revoked or cancelled, or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction against which appeal is not, or is no longer, possible or that has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, or disclaimer or otherwise; or (b) a pending patent application in the Territory being prosecuted in good faith that has not been cancelled, withdrawn, abandoned, finally rejected and that has not been pending for more than [***] ([***]) years from the date of its first priority filing anywhere in the world. If a claim of a patent application that ceased to be a Valid Claim under item (b) because of the passage of time that later issues as part of a patent within item (a), then it shall again be considered a Valid Claim effective as of the earlier of the grant, allowance or issuance of such patent.

2. LICENSES

2.1 License Grants. Subject to the terms of this Agreement, Licensor hereby grants to Licensee a license, with the right to grant sublicenses pursuant to Section 2.2 (Sublicensing), under the Licensed Technology to: (a) Commercialize Licensed Products and to otherwise exploit the Licensed Technology in the Territory on an exclusive basis (including with regard to Licensor, Biocon, Nobex and their respective Affiliates); and (b) use, research, Develop, export and make and have made Licensed Products worldwide for purposes of clause (a) above, on a non-exclusive basis.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

2.2 Sublicensing. Licensee may sublicense only in the Territory the rights granted to it under Section 2.1 (License Grants) through one or more tiers to one or more of its Affiliates or Third Parties at any time. Any such sublicense must be in writing, and shall be consistent with the terms of this Agreement. If this Agreement terminates for any reason, any sublicense granted by the Licensee under this Agreement shall survive such termination provided that such sublicense shall be automatically assigned by the Licensee to Licensor upon such termination, and at no cost to Licensor, provided further that any sublicense granted by the Licensee under this Agreement that contains any provision preventing such assignment, shall stand terminated promptly and automatically from the effective date of the termination of this Agreement.

2.3 No Other Licenses. Except for the license rights granted under this Article 2, Licensor grants no other rights or licenses of whatsoever nature and Licensee shall not be entitled to any other right or license under this Agreement.

3. MILESTONE PAYMENTS

3.1 Initial Payment. Upon the earlier of (a) ten (10) days following the closing of Licensee's first equity financing that brings the total equity financing raised to [***] dollars ($[***]), or (b) the eighteen (18) month anniversary of the Effective Date, Licensee shall make a non-refundable payment of [***] dollars ($[***]) (the "Initial Payment") to the Licensor. In the event Licensee does not make the Initial Payment when it becomes due, Licensor's sole remedy shall be to terminate this Agreement upon thirty (30) days written notice; provided, however, that such termination shall not be effective if Licensee makes the Initial Payment prior to the expiration of such thirty (30) day notice period.

3.2 Development Milestone Payments. Licensee shall pay to Licensor, without any offset, non-refundable, one-time milestone payments specified below with respect to the Development by Licensee and its Sublicensees of a Licensed Product as a human therapeutic no later than forty (40) days after the following events have each initially occurred. Licensee will only pay each of the Development milestones listed below once.

Apaza Milestone Event	**Milestone Payment**
[***]	[***]
First filing of an NDA with the FDA and acceptance by FDA of such NDA	$ 1,000,000
[***]	[***]
[***]	[***]
[***]	[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

3.3 Commercialization Milestone Payments. Licensee shall pay to Licensor, without any offset, non-refundable, one-time milestone payments specified below with respect to the Commercialization by Licensee and its Sublicensees of Licensed Products as a human therapeutic no later than forty (40) days after the following events have each initially occurred. Licensee will only pay each of the Commercialization milestones listed below once.

Apaza Milestone Event	**Milestone Payment**
Upon aggregate Net Sales of Licensed Products in the Territory reaching [***] Dollars (US$[***]) in a single calendar year	$ 2,000,000
Upon aggregate Net Sales of Licensed Products in the Territory reaching [***] Dollars (US$[***]) in a single calendar year	$ 2,500,000
Upon aggregate Net Sales of Licensed Products in the Territory reaching [***] Dollars (US$[***]) in a single calendar year	$ 1,000,000

4. ROYALTIES

4.1 Royalty Payment on Net Sales. During the relevant Royalty Term, for each Licensed Product in the Territory, Licensee shall pay or cause to be paid to Licensor a royalty on Net Sales of Licensed Products made by Licensee, its Affiliates and its Sublicensees at the following rates:

4.1.1 [***] percent ([***]%) of the first [***] Dollars ($[***]) of Net Sales made in the Territory during a calendar year; and

4.1.2 [***] percent ([***]%) of Net Sales made in the Territory during a calendar year in excess of [***] Dollars ($[***]); provided, however, that in the event a generic for a Licensed Product is launched in a country in the Territory, Licensee's royalty obligation with respect to sales in such country shall be reduced by [***] percent ([***]%) (i.e., upon launch of a generic for the Licensed Product in a country, the royalty rates set forth above shall be [***]% and [***]% respectively in such country). The term "generic" refers to a product that has the same or substantially the same active ingredient(s), in the same or substantially the same dosage form and strength.

4.2 Non-Royalty Sublicensing Revenue. For each sublicense that Licensee or its Affiliates grants pursuant to Section 2.2 above, Licensee shall pay to Licensor [***] percent ([***]%) of Non-Royalty Sublicensing Revenue (with such portion referred to as "Sublicensing Proceeds") received by Licensee or its Affiliates during the Royalty Term on a product-by-product, country-by-country basis. Sublicensing Proceeds, if any, for any Licensed Product shall be credited towards any amounts that Licensee otherwise owed to, or that subsequently become due to, Licensor under Section 3 and Section 4.1.

4.3 Royalty Term. For each Licensed Product, the obligation of Licensee to pay Licensor royalties with respect to a given country in the Territory shall commence on the date of the First Commercial Sale of such Licensed Product by the Licensee or its Affiliates or Sublicensee in such country and shall continue until the earlier of (i) the date of expiration of the last to expire Valid Claim for such Licensed Product (in the case of the U.S., based on the FDA's Orange Book), and (ii) the date that one or more generic equivalents of the Licensed Product in the aggregate makes up fifty percent (50%) or more of sales in the applicable country in a calendar year (the "Royalty Term"). Upon Expiration of the applicable Royalty Term in any country, the license granted pursuant to Section 2.1 shall become irrevocable and royalty-free in such country.

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4.4 Compulsory Licenses. If Licensee is required to grant a compulsory license to a Third Party as required by the applicable laws of any country in the Territory under the Licensed Patents, and the royalty rate payable to Licensee for sales of Licensed Product by such Third Party is lower than the royalty rate payable by Licensee to Licensor for such sales, then the royalty rate payable hereunder by Licensee for sales of Licensed Products by such Third Party in such country shall be no greater than the rate payable by such Third Party to Licensee for such country.

4.5 Third Party Royalty Obligations. If (a) in order to avoid infringement of any patent not licensed hereunder, Licensee reasonably determines that it is necessary to obtain a license from a Third Party in order to Develop or Commercialize a Licensed Product in a country in the Territory and to pay a royalty or other consideration under such license (including in connection with the settlement of a patent infringement claim), or (b) Licensee shall be subject to a court or other similar binding order or ruling requiring any payments, including the payment of a royalty to a Third Party patent holder in respect of sales of any Licensed Product in a country in the Territory, then the amount of Licensee's payments with respect to Net Sales for such Licensed Product in such country, prior to the application of any credits, shall be reduced by [***] percent ([***]%) of the amounts payable to such Third Party. Licensee shall have the right to carry forward and apply any unused offset or deduction to which Licensee is entitled under this Section 4.5, against future royalties or other payments due to Licensor under Section 4.1 until the full amount of the offset or deduction to which Licensee is entitled is satisfied, provided that the aggregate off-set in any calendar year for any Licensed Product shall not exceed [***] percent ([***]%) of the amounts payable for that Licensed Product in that calendar year, and provided further that any remaining off-set shall be offset in subsequent calendar years subject to the maximum aggregate off-set in any calendar year not exceeding [***] percent ([***]%) of the amounts payable for that Licensed Product in that calendar year.

5. MILESTONE AND ROYALTY REPORTS AND ACCOUNTING

5.1 Reports and Payments.

5.1.1 Royalty Payments and Statements. With respect to each Licensed Product, after the First Commercial Sale and until the Royalty Term expires, Licensee shall deliver to Licensor within forty (40) days after the end of each calendar year, the total royalties due from Licensee to Licensor for such year, along with a report setting forth for such year the following information:

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(a) the gross sales and Net Sales of each Licensed Product in the Territory in local currency and in U.S. Dollars;

(b) information regarding any compulsory licenses, Third Party licenses or other deductions or set-offs described in Section 4;

(c) the Sublicensing Proceeds received by Licensee;

(d) the calculation of net royalty due from Licensee under Section 4.1 payable in U.S. Dollars;

(e) withholding taxes, if any, required by law to be deducted with respect to such Net Sales; and

(f) the calculation of the conversion of payments into U.S. Dollars, if applicable.

5.1.2 Milestone Payments and Statements. Licensee shall notify Licensor of the occurrence of each milestone event and shall make milestone payments to Licensor as described in Section 3 above. Upon Licensor's request from time to time, but not more than once in any three month period, Licensee shall provide Licensor with an update on the status of its Development activities related to such milestone events.

5.1.3 Taxes and Withholding. All amounts payable by Licensee to Licensor or its designee pursuant to this Agreement ("Payments") are inclusive of, and shall be made subject to any deduction or withholding for or on account of, any Tax required by applicable laws or regulations. Licensee shall not be required to gross up any Payments or to pay any additional amounts to account for such deduction or withholding. Licensor (or its Affiliates) alone shall be responsible for paying any and all Taxes levied on account of, or measured in whole or in part by reference to, any Payments they receive If Licensee does deduct or withhold as set forth above, Licensee shall (i) promptly notify Licensor of such deduction or withholding, (ii) pay to the relevant authorities the full amount deducted or withheld, and (iii) promptly forward to Licensor an official receipt (or certified copy) or other documentation evidencing such payment to such authorities Licensor retains the right to respond to and challenge any such Tax.

5.1.4 Currency. All dollar amounts set forth herein and all Payments required under this Agreement shall be made in U.S. Dollars. For the purpose of computing the Net Sales of Licensed Products received in a currency other than U.S. Dollars, such amount shall be converted from local currency to U.S. Dollars by Licensee using the average rate of exchange for such currencies for the relevant period as sourced from www.oanda.com. Licensee may modify the currency conversion methodology from time to time, provided that Licensee obtains Licensor's prior written consent, which shall not be unreasonable withheld or delayed, and provided that any such modification apply prospectively only.

5.1.5 Delayed Payment. In the event Licensee fails to make, defaults in making or otherwise delays the making of any Payments pursuant to this Agreement for more than thirty (30) days after the due date, Licensee shall pay such amount to Licensor plus interest, which shall accrue at a rate of [***] % per month compounded monthly ([***]% per annum) until such unpaid portion is paid to Licensor in full, and Licensee shall be responsible for reasonable legal fees and expenses incurred by Licensor in connection with the collection thereof.

5.2 Maintenance of Records; Audits.

5.2.1 Record Keeping and Audits. Licensee shall keep and shall cause its Affiliates and sublicensees to keep books and accounts of record in connection with the sale of Licensed Products and in sufficient detail to permit accurate determination of all figures necessary for verification of all Payments to be paid hereunder. Such books and records shall be made available upon Licensor's reasonable request (but not more than once in any twelve month period) and at Licensor's expense for inspection by Licensor's independent auditors that are reasonably acceptable to Licensee. Such inspections shall be during normal business hours, at times mutually acceptable to both Parties, and last no longer than two (2) business days. Such auditors must have agreed in writing to maintain all information learned in confidence, except as necessary to disclose to Licensor such compliance or noncompliance by the Licensee. Licensee and its Affiliates shall maintain such records for a period of at least two (2) years after the end of the period for which they were generated or longer if required by law or regulation, and Licensee shall procure that all Sublicensees of Licensee or its Affiliates maintain such records for a period of at least two (2) years after the end of the period for which they were generated or longer if required by law or regulation.

5.2.2 Underpayments/Overpayments.

(a) If any audit by Licensor's auditors concludes that additional Payments were due by Licensee to Licensor, Licensee shall pay to Licensor the additional Payments within thirty (30) days of the date Licensee receives notice from Licensor of such conclusion, with interest from the date such amount should have been due at a rate of [***]% per month compounded monthly ([***]% per annum) until such unpaid portion is paid to Licensor in full. Any such underpayment that exceeds [***] percent ([***]%) of the amount actually due to Licensor for the year under audit shall be considered a "Material Underpayment." If Licensee makes a Material Underpayment more than once, Licensee shall reimburse Licensor for the actual cost of the audit for such period or US$[***], whichever is less. For the avoidance of doubt, Licensee shall have no obligation to reimburse audit costs related to the first Material Underpayment, if any.

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(b) If such audit concludes that Licensee overpaid any Payments to Licensor, Licensor shall refund such overpayments to Licensee, within thirty (30) days of the date of the conclusion of such audit.

5.3 Disputes. In the event that Licensee disputes in good faith any Payment amount that Licensor claims to be due pursuant to this Agreement, Licensee may withhold payment of such disputed amount, provided; however, that if any such disputed amount is ultimately paid, Licensee shall pay such amount to Licensor plus interest and reasonable legal fees and expenses incurred by Licensor in connection with the collection thereof all in accordance with Section 5.1.5. Any Payment dispute shall be submitted to an independent accounting firm mutually acceptable to the Parties for resolution. Licensee and Licensor shall instruct the independent accounting firm to resolve such disputed matter within forty-five (45) days of having the disputed matter referred to it, and in connection therewith, each Party shall use commercially reasonable efforts to cooperate with the independent accounting firm. The independent accounting firm's determination of the disputed matter referred to it shall be final and binding upon the Parties, and any amount shown due by such determination shall be paid by the Party owing such amount within twenty (20) days after such determination, and the Parties shall share the cost of such independent accounting firm's review equally.

6. REGULATORY MATTERS

6.1 Transfer of the Product Regulatory Findings; Technical Assistance. Promptly following the Effective Date, the Parties shall file, and shall cause their Affiliates and agents to file, with the FDA, the EMEA and any other relevant Regulatory Authority all of the documents and information required by the Regulatory Authorities to effect the transfer of the Regulatory Filings in the Territory to Licensee or an Affiliate or agent of Licensee designated by Licensee. To Licensor's knowledge, all such Regulatory Filings are described on Exhibit B. Promptly following the Effective Date, Licensor shall transfer, and shall cause its Affiliates and agents to transfer to Licensee, all of the documents and the information described in Exhibit B in accordance with any applicable Regulatory Authorities' guidelines. Licensor shall file a letter with Regulatory Authorities acknowledging the transfer of ownership of the Regulatory Filings, and Licensee shall file the information required of a new owner. Each of Licensee and Licensor shall take, and shall cause their respective Affiliates and agents to take, any and all other actions required by the Regulatory Authorities to effect the transfer of the Regulatory Filings from Licensor or its Affiliates or agents to Licensee or its designated Affiliate or agents as soon as reasonably practicable. Licensor shall be entitled to obtain and retain at its expense an archival copy of the Regulatory Filings in existence on the Effective Date, including supplements and records that are required to be kept under applicable law. In the event that Licensor locates or obtains any additional information related to Apaza Compound or Licensed Product (including without limitation any information identified on Exhibit B as "empty" or "missing"), Licensor shall promptly provide such information to Licensee. From the Effective Date until the First Commercial Sale of Licensed Product, Licensor agrees to make available to Licensee those personnel of Licensor knowledgeable with respect to the development of Apaza Compound (including [***] and [***]) as requested by Licensee for consulting or technical help regarding Licensed Product. Licensor shall be entitled to reasonable, mutually agreed compensation for the provision of such services. Licensor further agrees that in the event that such personnel cease to be employed by Licensor, Licensee may engage such personnel and such persons may provide assistance to Licensee or its designees related to Licensed Product without restriction of any confidentiality, noncompetition or similar obligation.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

6.2 Responsibility for the Products. Form and after the Effective Date, Licensee shall have all regulatory responsibilities under applicable laws and regulations, reporting and otherwise, in connection with the Licensed Products in the Territory.

6.3 Communications with Regulatory Agencies. From and after the Effective Date, Licensee shall have responsibility for all communication with the FDA and other applicable Regulatory Authorities with respect to all matters relating to the Licensed Products in the Territory, and Licensor shall not make any such communications with the FDA or other applicable Regulatory Authority without the prior written consent of Licensee. From and after the Effective Date, each Party shall, or shall cause its Affiliates or agents to, promptly make available to the other Party copies of all correspondence with any Regulatory Authority regarding regulatory warning letters, withdrawal of any Licensed Product, and correspondence bearing on the safety and efficacy of the Licensed Product.

6.4 Additional Information. From and after the Effective Date and at Licensor's expense, Licensor shall, and shall cause its Affiliates and agents to, undertake good faith efforts to provide to Licensee information existing on the Effective Date and Controlled by Licensor that Licensee reasonably requests regarding the Development of the Licensed Products and which is needed for Licensee to comply with applicable reporting requirements of the FDA and other Regulatory Authorities in the Territory.

6.5 Government Approvals. At Licensee's expense, Licensor and its Affiliates and agents shall cooperate with the other Party and use commercially reasonable efforts to make all registrations, filings and applications, to give all notices and to obtain as soon as practicable all governmental and other consents, transfers, approvals, orders, qualifications, authorizations, permits and waivers, if any, and to do all other things necessary or desirable for the consummation of the transactions as contemplated by this Agreement.

7. DEVELOPMENT AND COMMERCIALIZATION

7.1 Development and Commercialization.

7.1.1 Licensee Responsibility. Licensee shall have the sole responsibility, authority and discretion to Develop, seek Regulatory Approvals for and Commercialize the Licensed Products in the Territory and to make all decisions relating to such matters, including termination.

7.1.2 United States. Subject to Section 7.2 below, Licensee shall use commercially reasonable efforts to Develop and Commercialize the Licensed Products in the United States.

7.2 Abandoned Products and Countries. Licensee may, in its sole discretion and for whatever reason, discontinue Development or Commercialization of a Licensed Product in a particular country in the Territory. In such event, Licensee shall promptly notify Licensor of its decision and the Parties shall terminate this Agreement with respect to affected Licensed Products in affected countries in accordance with Section 13.2.2 below.

7.3 Ownership of Licensee Improvements. Title to all Improvements conceived solely by or on behalf of Licensee ("Licensee Improvements") shall be owned exclusively by Licensee. Title to all Improvements conceived by Licensor personnel ("Licensor Improvements") shall be owned exclusively by Licensor; provided, however, that Licensor Improvements shall be subject to the license granted to Licensee pursuant to Section 2.1. Title to all Improvements conceived jointly by Licensee personnel and Licensor personnel ("Joint Improvements") shall be owned jointly by Licensee and Licensor; provided, however, that Licensor's interest in Joint Improvements shall be subject to the license granted to Licensee pursuant to Section 2.1.

7.4 Non-Competition Applicable to Licensor. For [***] ([***]) years following the Effective Date, Licensor covenants that it shall not, and shall cause its Affiliates not to, engage in a Competing Business, directly or indirectly, including the sublicensing of rights to engage in a Competing Business. Licensor acknowledges that the noncompetition and other restrictive covenants and agreements set forth in this Agreement are necessary to protect the rights being granted to Licensee pursuant to this Agreement, and are reasonable in scope.

7.5 Non-Competition Applicable to Licensee. During [***], Licensee covenants that it shall not, and shall cause its Affiliates not to, engage in a Biocon Competing Business (as defined below), directly or indirectly [***]. For the purpose of this paragraph, a "Biocon Competing Business" means [***]. Licensee acknowledges that the noncompetition and other restrictive covenants and agreements set forth in this Agreement are necessary to protect the rights being granted to Licensee pursuant to this Agreement, and are reasonable in scope. Notwithstanding the foregoing, the Agreement shall not preclude Licensee or any of its Affiliates from owning or acquiring 5% of the outstanding equity securities in any publicly traded company that engages in a Biocon Competing Business or acquiring an ownership interest in any company that engages in a Biocon Competing Business where the competition is not material to Biocon or where Licensee agrees to divest and does divest such Biocon Competing Business as soon as commercially reasonable but in no event more than two years from the date the acquisition is consummated.

7.6 Licensee's Clinical Data. The parties acknowledge that as a result of this Agreement, Licensee may generate clinical trial data relating to the Licensed Products ("Licensee Clinical Data"), which shall be owned by Licensee and shall be considered Licensee's Confidential Information.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

7.7 No Implied Obligation. Licensor acknowledges and agrees that nothing in this Agreement shall be construed as representing an estimate or projection of the anticipated development, approvals or sales of any Licensed Product. LICENSEE MAKES NO REPRESENTATION OR WARRANTY THAT IT SHALL SUCCEEED IN THE DEVELOPMENT OR COMMERCIALIZATION ACTIVITIES, ACHIEVING ANY MILESTONE OR ACHIEVING ANY PARTICULAR SALES LEVEL OF SUCH LICENSED PRODUCTS. Licensor acknowledges and agrees that except as expressly set forth herein, Licensee has no duties or obligations to Licensor or its Affiliates, and is not a fiduciary of Licensor or its Affiliates.

7.8 Adverse Event Reporting. If Licensee elects to Commercialize a Licensed Product, the Parties will prepare a standard operating procedure governing the collection, investigation, reporting, and exchange of information concerning adverse drug reactions, quality and other complaints, sufficient to permit each Party to comply with its legal and regulatory obligations. Such standard operating procedure will be promptly updated if required by changes in legal or regulatory requirements. Subject to the foregoing, each Party shall promptly inform the other Party about any adverse drug reactions, as well as any non-adverse serious (e.g. from Licensed Product overdose) and any toxicity, sensitivity, failure of expected pharmacological action, or laboratory abnormality which is, or is thought by the reporter, to be serious or associated with relevant clinical signs or symptoms, in each case of which such Party becomes aware or is informed about regarding the use of a Licensed Product. Each Party shall ensure that is Affiliates and sublicensees shall comply with the foregoing obligations as if a Party.

8. PATENT RIGHTS

8.1. Licensed Patents in the Territory.

8.1.1 Ownership, Prosecution and Maintenance of Licensed Patents in the Territory. Subject to Section 8.1.2, Licensee shall have the first right, but not the obligation, at its sole expense, to prosecute any and all patent applications within the Licensed Patents and all patentable inventions included in Licensor Improvements, Licensee Improvements and Joint Improvements, in each case, in the Territory with respect to Licensed Patents and Licensor Improvements and worldwide with respect to Licensee Improvements and Joint Improvements, including but not limited to, the right to conduct interferences, oppositions, reissue proceedings and reexaminations, to obtain patents thereon, and to maintain all patents included therein. Such prosecution and maintenance may be performed by outside counsel of Licensee's choosing. Licensor's comments regarding the choice of such outside counsel shall be considered, but Licensee's decision in this regard shall be final. Licensor will not file any additional patents claiming any compound related to the Apaza Compound without prior consent from Licensee. Licensee shall keep Licensor fully informed in a timely manner, and, as is reasonably practicable, of the progress regarding the prosecution of each patent application included within the Licensed Patents and patent applications with respect to Joint Improvements and Licensor Improvements. Licensor shall have the right to review all pending patent applications and other proceedings, and to make recommendations to Licensee regarding the prosecution of such patent applications; provided that all final decisions regarding the prosecution and maintenance of such patent applications shall be made by Licensee.

8.1.2 Discontinuation; Abandonment of Licensed Patents in the Territory. If Licensee wishes to discontinue the prosecution of any patent application or to abandon any patent within the Licensed Patents or patentable inventions included in Licensor Improvements or Joint Improvements, Licensee shall inform Licensor at least ninety (90) days prior to such discontinuance and Licensor shall, at its option, have the exclusive right to prosecute such patent application and/or maintain such patent at its expense prior to the date that such discontinuance would otherwise take effect, and such Patent Rights included in the Licensed Patents and related to Licensor Improvement and Joint Improvements shall stand excluded from the license granted to the Licensee under this Agreement, and Exhibit A shall stand automatically and accordingly amended, notwithstanding any provisions to the contrary under this Agreement. Licensor shall advise Licensee in writing of its decision regarding the opportunity to prosecute and/or maintain such application or patent within thirty (30) days of the date of discontinuance and in the absence of a written decision from Licensor, Licensee shall have the right to discontinue or abandon such application or patent. In the event Licensor timely elects to prosecute and maintain such patent or patent application, Licensee shall, if required, execute an assignment transferring ownership of any patent or patent application to Licensor in each such country. Licensee's cancellation or amendment of a claim or claims during the prosecution of a patent application in a country within the Licensed Patents or a patent application with respect to a Licensor Improvement or Joint Improvement in the Territory shall not constitute a discontinuance or abandonment under this section, provided that such cancellation or abandonment does not prejudice the ability to obtain granted claims to the cancelled subject matter in a related continuation, divisional, or other application in such country.

8.3 Status of Patents; Other Actions.

8.3.1 Initial. Prior to the Effective Date, Licensor advised Licensee as to the current status of any patent applications and patents included within the Licensed Patents, and, as of the Effective Date, there has been no change. To the extent it has not previously done so, Licensor shall promptly make available to Licensee on a confidential basis, and subject to the other provisions of this Agreement, all documentation Controlled by Licensor and relating to such patent applications and patents, including, but not limited to, copies of all patent applications, relevant prior art, search reports, freedom to operate analyses or opinions, official actions and examination reports, and all correspondence to and from local agents or attorneys responsible for local prosecution of such applications.

8.3.2 Ongoing. At any time upon a Party's request, and no more than four (4) times per calendar year, each Party shall, within thirty (30) days: (i) advise the other Party as to the then-current status of any patent applications or patents within the Licensed Patents specifically relevant to any Licensed Product; and (ii) to the extent the other Party requests, make available to the other Party materially relevant documentation relating to such patent applications and patents, including, but not limited to, copies thereof.

8.3.3 Notices. Licensor will execute and file at Licensee's expense those notices and other filings as Licensee shall reasonably request be made, from time to time with any patent office or patent agency in the Territory, and in all other respects shall reasonably cooperate with Licensee, to effect the further prosecution and maintenance of Patent Rights associated with the Licensed Patents, Licensor Improvements and Joint Improvements, and the other rights granted to Licensee under this Agreement. Licensee will execute and file at Licensor's expense those notices and other filings as Licensor shall reasonably request be made, from time to time with any patent office or patent agency outside the Territory, and in all other respects shall reasonably cooperate with Licensor, to effect the further prosecution and maintenance of the Licensed Patents outside the Territory.

8.3.4 Power of Attorney. Upon the Effective Date, Licensor shall execute, and shall cause Biocon to execute, as applicable, a specific power of attorney in favor of Licensee (or any Affiliate or agents as directed by Licensee) for purposes of prosecution and maintenance of the Patent Rights associated with the Licensed Patents, Licensor Improvement or Joint Improvement, and taking other actions contemplated by this Agreement.

8.4 Patent Term Extension. Licensee shall have the exclusive right to seek, at Licensee's expense, patent term extensions or supplemental patent protection, including supplementary protection certificates, in any country in the Territory in relation to the Licensed Products. Licensor and Licensee shall cooperate in connection with all such activities, and Licensee, its agents and attorneys will give due consideration to all timely suggestions and comments of Licensor regarding any such activities; provided that all final decisions in this regard shall be made by Licensee.

8.5 Orange Book Listings for Licensed Patents. With respect to filings in the FDA Orange Book (and foreign equivalents) for issued patents for a Licensed Product, Licensee shall be solely responsible at its expense for fulfilling its obligations under applicable law to list any applicable Licensed Patents in a timely manner and make all applicable filings regarding the Licensed Patents required to be filed by it under applicable law. Licensee will be solely responsible for any such filings and listings, and for any and all decisions with respect to such filings and listings.

8.6 Notification of Patent Certification for Licensed Patents. If a Party becomes aware that any certification filed pursuant to 21 U.S.C. § 355(b)(2)(A) or 355(j)(2)(A)(vii)(IV), or any notice under any future analogous provisions of United States law relating to regulation or approval of drug products (or any amendment or successor statute thereto) claiming that any Licensed Patents covering a Licensed Product are invalid or otherwise unenforceable, or that infringement will not arise from the manufacture, use, import or sale of a product by a Third Party, such Party shall promptly notify the other Party in writing after its receipt thereof.

8.7 Limitation on Patent Actions. Neither Party shall be required to take any action pursuant to Sections 8.4, 8.5 or 8.6 hereof that such Party reasonably determines in its sole judgment and discretion conflicts with or violates any court or government order or decree that such Party is then subject to or otherwise may create legal liability on the part of such Party.

8.8 Registration of License. Licensor hereby authorizes Licensee to record a brief, mutually acceptable memorandum disclosing the existence of this Agreement and the license granted herein in the title records of the relevant patent to the extent required for the licenses granted herein to be effective against Third Parties under applicable law. Any such recordation shall disclose as little regarding the terms and conditions of this Agreement as necessary to properly register or record this Agreement under applicable law.

9. INFRINGEMENT

9.1 Notice. Each Party shall promptly report in writing to the other Party any known or suspected (i) infringement of any of the Patents Rights associated with the Licensed Patents, Licensor Improvements, Licensee Improvements and Joint Improvements, or (ii) unauthorized use or misappropriation of any of the Apaza Know-How of which such Party becomes aware, and shall provide the other Party with all available evidence supporting such known or suspected infringement or unauthorized use.

9.2 Third Party Infringement in the Territory. If a Third Party infringes any of the Patent Rights associated with the Licensed Patents, Licensor Improvements, Licensee Improvements or Joint Improvements in the Territory, Licensee will have the first right (but not the obligation), at its own expense, to pursue any and all injunctive relief, and any or all compensatory and other remedies and relief (collectively, "Remedies"), against such Third Party, and Licensor will have the right to participate in such action at its own expense. Should Licensee determine not to pursue Remedies with respect to any such infringement or misappropriation of Licensed Technology, Licensor Improvements or Joint Improvements within thirty (30) days after receipt of written notice from Licensor requesting Licensee to do so, then, unless Licensee is engaged in active negotiations regarding the grant of a sublicense to the infringer, Licensor will have the right (but not the obligation), at its own expense, to pursue Remedies against such Third Party, and Licensee shall have the right to participate in such action at its own expense. If a Party pursues Remedies hereunder with respect to infringement or misappropriation, the other Party will use all reasonable efforts to assist and cooperate with the Party pursuing such Remedies, including joining in any action or providing a power of attorney if necessary. Each Party will bear its own costs and expenses relating to such pursuit. Any damages or other amounts collected will be distributed, first, to the Party that pursued Remedies to cover its costs and expenses; and second, to the other Party to cover its costs and expenses, if any, relating to the pursuit of such Remedies; and any remaining amount will be distributed to the Party or Parties that pursued the Remedies. [***].

9.3 Third Party Invalidity Claim. Each of the Parties shall promptly notify the other in the event of any legal or administrative action by any Third Party against Patents Rights associated with the Licensed Patents, Licensor Improvements, Licensee Improvements or Joint Improvements in the Territory of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. Licensee shall have the first right, but not the obligation, to defend against any such action involving such Patent Rights in the Territory in its own name, and the costs of any such defense shall be at Licensee's expense. Licensor, upon request of Licensee, agrees to join in any such action and to cooperate reasonably with Licensee; provided that Licensee shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Licensor in connection with such cooperation. If Licensee does not defend against any such action involving a Licensed Patent, Joint Improvement or a Licensor Improvement in the Territory, then Licensor shall have the right, but not the obligation, to defend such action and any such defense shall be at Licensor's expense. Licensee, upon request of Licensor, agrees to join in any such action and to cooperate reasonably with Licensor; provided that Licensor shall promptly reimburse all out-of-pocket expenses (including reasonable counsel fees and expenses) actually incurred by Licensee in connection with such cooperation. [***].

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

9.4 Infringement of Third Party Rights. Each Party shall promptly notify the other in writing of any allegation by a Third Party that the activity of either of the Parties or their Affiliates or a Sublicensee in connection with the Development or Commercialization of the Licensed Products infringes the issued patent rights (or would infringe the claims, if issued, of a pending patent application) of any Third Party in the Territory ("Patent Claims"). In the event of a litigation in accordance with this Section 9.4, Licensee shall have the right, but not obligation, to defend and/or settle any such Patent Claims. Notwithstanding the foregoing, in the event Licensor determines in its reasonable judgment that Licensee is not using diligent efforts to defend and/or settle any such Patent Claim, Licensor may, but shall not be required to, take over the defense or settlement negotiations upon written notice to Licensee at Licensor's sole cost and expense.

10. REPRESENTATIONS, WARRANTIES, AND COVENANTS

10.1 Representations Warranties and Covenants of Each Party. Each Party hereby represents, warrants and covenants to the other Party as follows:

10.1.1 Such Party: (a) is duly formed and in good standing under the laws of the jurisdiction of its formation; (b) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; and (c) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms.

10.1.2 All necessary consents, approvals and authorizations of all Regulatory Authorities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained except for Regulatory Approvals for the Commercialization of the Product.

10.1.3 The execution and delivery of this Agreement, the performance of such Party's obligations hereunder, and any actions or omissions of such Party related to the activities contemplated hereunder and the circumstances surrounding this Agreement: (a) do not and will not conflict with or violate any applicable law or any provision of the articles of incorporation, bylaws or other governing charter documents of such Party; and (b) do not and will not conflict with, violate, or breach, or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound.

10.1.4 Each Party agrees not to engage in any action that is in violation or inconsistent with the terms and conditions of this Agreement or that interferes with the consummation of the transactions contemplated under this Agreement.

10.1.5 Neither Party nor any of its Affiliates is a Party to or otherwise bound by any oral or written contract or agreement that will result in any Third Party obtaining any interest in, or that would give to any Third Party any right to assert any claim in or with respect to, any of the Parties' rights under this Agreement.

10.2 Additional Licensor Representations, Warranties and Covenants. Licensor represents, warrants and covenants to Licensee as follows:

10.2.1 Licensor has not received and is not aware of any written notice of any claim by a Third Party alleging infringement or misappropriation of any intellectual property of any Third Party based on the Licensed Technology.

10.2.2 Licensor and its Affiliates have the right to grant the licenses granted to Licensee herein, and Licensor exclusively owns all right, title and interest in and to, or has an exclusive license or sublicense to use and license, all of the Licensed Technology.

10.2.3 To the best of Licensor's knowledge, the inventors listed in the Licensed Patents are the sole inventors with respect to inventions incorporated therein.

10.2.4 Licensor shall at all times comply with the terms of and its obligations under the Biocon License Agreement, and shall not agree to amend the Biocon License Agreement without the prior written consent of Licensee.

10.2.5 To the best of Licensor's knowledge, the Licensed Technology is free from all Liens or encumbrances of any kind.

10.2.6 It shall not, and it shall cause its officers, employees and subcontractors not to, make any untrue statement of material fact to any Regulatory Authority with respect to the Licensed Products, or knowingly fail to disclose a material fact required to be disclosed to any Regulatory Authority with respect to the Licensed Products.

10.2.7 It shall not employ any personnel, or knowingly use a contractor or consultant, debarred by the FDA (or subject to a similar sanction of a Regulatory Authority outside the United States), or who is subject of an FDA debarment investigation or proceeding (or similar proceeding of a Regulatory Authority outside the United States).

10.3 Additional Licensee Representations, Warranties and Covenants. Licensee represents, warrants and covenants to Licensor as follows:

10.3.1 It shall not, and it shall cause its officers, employees and subcontractors not to, make any untrue statement of material fact to any Regulatory Authority with respect to the Licensed Products, or knowingly fail to disclose a material fact required to be disclosed to any Regulatory Authority with respect to the Licensed Products.

10.3.2 It shall not employ any personnel, or knowingly use a contractor or consultant, debarred by the FDA (or subject to a similar sanction of a Regulatory Authority outside the United States), or who is subject of an FDA debarment investigation or proceeding (or similar proceeding of a Regulatory Authority outside the United States).

10.4 Disclaimer. EXCEPT AS OTHERWISE SPECIFICALLY SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, ARISING BY LAW OR OTHERWISE, AND BOTH PARTIES HEREBY DISCLAIM ALL IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, (I) ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, (II) ANY IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OF TRADE, (III) IMPLIED WARRANTY OF NONINFRINGEMENT, AND (IV) IMPLIED WARRANTY OF TITLE.

11. INDEMNIFICATION

11.1 Indemnification by Licensee. Licensee shall defend, indemnify and hold harmless Licensor and its Affiliates and each of their respective officers, directors, shareholders, employees, successors and assigns from and against all claims or demands made by a Third Party ("Third Party Claims"), and all associated Losses, to the extent arising out of: (a) a breach of this Agreement by Licensee; (b) the development, testing, manufacture, storage, use, handling, distribution, labeling, promotion, marketing, sale or other disposition of any Licensed Product or component thereof by Licensee after the Effective Date; or (c) the Commercialization of the Licensed Products in the Territory; provided, however, that in case of (b) or (c) of this Section 11.1, Licensee shall not be liable to indemnify Licensor for any Losses to the extent that such Losses were caused by (i) the negligence or willful misconduct or intentional wrongdoing of Licensor, its Affiliates or their respective employees or contractors, or (ii) any breach of this Agreement by Licensor, or (iii) the Licensed Technology infringing upon the intellectual property rights of any Third Party.

11.2 Indemnification by Licensor. Licensor shall defend, indemnify and hold harmless Licensee and its Affiliates and each of their respective officers, directors, shareholders, employees, successors and assigns from and against all Third Party Claims, and all associated Losses, to the extent arising out of: (a) the negligence or willful misconduct of Licensor, its Affiliates or their respective employees or contractors in performing any of its obligations under this Agreement; (b) a breach of this Agreement by Licensor; (c) any payment obligations under or pursuant to the Biocon Agreement; or (d) any use of or activity related to Licensed Product prior to the Effective Date.

11.3 Biocon License Agreement. For the avoidance of doubt, Licensor shall be solely liable for all payment obligations under and pursuant to the Biocon License Agreement, and Licensee shall have no obligation with respect thereto. Without limiting the foregoing and without creating any future course of dealing between the Parties, Licensee may, but shall not be obligated to, make any payment due hereunder directly to Biocon in satisfaction of Licensor's obligation thereunder, and Licensee may credit any such amount so paid against any amounts due and payable hereunder to Licensor.

11.4 Procedure for Indemnification.

11.4.1 Notice. In the case of a Third Party Claim for which a Party (the "Indemnitor") may be obligated to provide indemnification pursuant to this Agreement, such Person seeking indemnification hereunder ("Indemnitee") will notify the Indemnitor in writing of the Third Party Claim (and specifying in reasonable detail the factual basis for the Third Party Claim and to the extent known, the amount of the Third Party Claim) reasonably promptly after becoming aware of such Third Party Claim; provided, however, that failure to give such notification will not affect the indemnification provided hereunder except to the extent the Indemnitor shall have been actually materially prejudiced as a result of such failure.

11.4.2 Defense of Claim. If a Third Party Claim is made against an Indemnitee, the Indemnitor will be entitled, within thirty (30) days after receipt of written notice from the Indemnitee of the commencement or assertion of any such Third Party Claim, to assume the defense thereof by providing written notice to Indemnitee of its intention to assume the defense of such Third Party Claims within such thirty (30) day period (at the expense of the Indemnitor) with counsel selected by the Indemnitor and reasonably satisfactory to the Indemnitee for so long as the Indemnitor is conducting a good faith and diligent defense. Should the Indemnitor so elect to assume the defense of a Third Party Claim, the Indemnitor will not be liable to the Indemnitee for any legal or other expenses subsequently incurred by the Indemnitee in connection with the defense thereof; provided, however, that if under applicable standards of professional conduct a conflict of interest exists between the Indemnitor and the Indemnitee in respect of such claim, such Indemnitee shall have the right to employ separate counsel to represent such Indemnitee with respect to the matters as to which a conflict of interest exists and in that event the reasonable fees and expenses of such separate counsel shall be paid by such Indemnitor; provided, further, that the Indemnitor shall only be responsible for the reasonable fees and expenses of one separate counsel for such Indemnitee. If the Indemnitor assumes the defense of any Third Party Claim, the Indemnitee shall have the right to participate in the defense thereof and to employ counsel, at its own expense, separate from the counsel employed by the Indemnitor. If the Indemnitor assumes the defense of any Third Party Claim, the Indemnitor will promptly supply to the Indemnitee copies of all correspondence and documents relating to or in connection with such Third Party Claim and keep the Indemnitee informed of developments relating to or in connection with such Third Party Claim, as may be reasonably requested by the Indemnitee (including, without limitation, providing to the Indemnitee on reasonable request updates and summaries as to the status thereof). If the Indemnitor chooses to defend a Third Party Claim, all Indemnitees shall reasonably cooperate with the Indemnitor in the defense thereof (such cooperation to be at the expense, including reasonable legal fees and expenses, of the Indemnitor). If the Indemnitor does not elect to assume control by written acknowledgement of the defense of any Third Party Claim within the thirty (30) day period set forth above, or if such good faith and diligent defense is not being or ceases to be conducted by the Indemnitor, the Indemnitee shall have the right, at the expense of the Indemnitor, after three (3) business days' written notice to the Indemnitor of its intent to do so, to undertake the defense of the Third Party Claim for the account of the Indemnitor (with counsel selected by the Indemnitee), and to compromise or settle such Third Party Claim, exercising reasonable business judgment.

11.4.3 Settlement of Claims. If the Indemnitor acknowledges in writing its obligation to indemnify the Indemnitee for a Third Party Claim, the Indemnitee will agree to any settlement, compromise or discharge of such Third Party Claim that the Indemnitor may recommend that by its terms obligates the Indemnitor to pay the full amount of Losses (whether through settlement or otherwise) in connection with such Third Party Claim and unconditionally and irrevocably releases the Indemnitee completely from all Losses in connection with such Third Party Claim; provided, however, that, without the Indemnitee's prior written consent, the Indemnitor shall not consent to any settlement, compromise or discharge (including, without limitation, the consent to entry of any judgment), that provides for injunctive or other nonmonetary relief affecting the Indemnitee.

11.5 Insurance. Immediately upon the First Commercial Sale of a Licensed Product in the Territory, during the Term and for a period of [***] ([***]) years after the termination or expiration of this Agreement, Licensee shall obtain and/or maintain at its sole cost and expense, product liability insurance (including any self-insured arrangements) in amount of no less than [***] dollars ($[***]). All insurance policies reflecting such insurance shall be written on a "per occurrence" or "claims made" basis with an insurance company rated at least A-3 by Best's rating guide. If requested, Licensee shall provide Licensor with a certificate of insurance and shall keep such policy current. Licensee shall use commercially reasonable efforts to ensure that each such insurance policy shall provide for at least thirty (30) calendar days prior written notice to Licensor of the cancellation or any substantial modification of the terms of coverage. Such product liability insurance (or self-insured arrangements) shall insure against all liability, including without limitation personal injury, physical injury, or property damage arising out of the manufacture, sale, distribution, or marketing of a Licensed Product.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

11.6 Limitation of Liability. EXCEPT (I) AS EXPRESSLY SET FORTH IN THIS AGREEMENT, (II) WITH RESPECT TO A PARTY'S INDEMNIFCATION OBLIGATIONS SET FORTH IN THIS SECTION 11, OR (III) TO THE EXTENT CAUSED BY FRAUD, GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OF ITS AFFILIATES FOR ANY LOST PROFITS OR REVENUES OR CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES.

12. CONFIDENTIALITY

12.1 General. Pursuant to the terms of this Agreement, each of Licensor and Licensee (in such capacity, the "Disclosing Party") has disclosed and will be disclosing to the other Party, and to the officers, directors, employees, agents and/or representatives of each (in such capacity, the "Receiving Party") its Confidential Information. The Receiving Party shall make no use of any Confidential Information of the Disclosing Party except in the exercise of its rights and the performance of its obligations set forth in this Agreement. The Receiving Party: (a) shall keep and hold as confidential, and shall cause its officers, directors, employees, agents and representatives to keep and hold as confidential, all Confidential Information of the Disclosing Party; and (b) shall not disclose, and shall cause its officers, directors, employees, agents and representatives not to disclose, any Confidential Information of the Disclosing Party. Confidential Information disclosed by the Disclosing Party shall remain the sole and absolute property of the Disclosing Party, subject to the rights granted in this Agreement.

12.2 Exceptions. The above restrictions set forth in Section 12.1 on the use and disclosure of Confidential Information shall not apply to any information which: (a) is already known to the Receiving Party at the time of disclosure by the Disclosing Party, as demonstrated by competent proof (other than as a result of prior disclosure under any agreement between the Parties with respect to confidentiality); (b) is or becomes generally known or available to the public other than through any act or omission of the Receiving Party in breach of this Agreement; (c) is acquired by the Receiving Party from a Third Party who is not directly or indirectly under an obligation of confidentiality to the Disclosing Party with respect to same, or (iv) is developed independently by the Receiving Party without the use, direct or indirect, of the Disclosing Party's Confidential Information. In addition, nothing in this Section 12 shall be interpreted to limit the ability of either Party to disclose its own Confidential Information to any other Person on such terms and subject to such conditions as it deems advisable or appropriate.

12.3 Permitted Disclosures. It shall not be a breach of Section 12.1 if a Receiving Party discloses Confidential Information of a Disclosing Party: (a) pursuant to applicable law, including securities laws, to any Regulatory Authority or the listing standards or agreements of any national or international securities exchange or The NASDAQ Stock Market or other governmental authority; or (b) in a judicial, administrative or arbitration proceeding to enforce such Party's rights under this Agreement; provided, however, that the Receiving Party (i) provides the Disclosing Party with as much advance written notice as possible of the required disclosure, (ii) reasonably cooperates with the Disclosing Party, at the Disclosing Party's expense, in any attempt to prevent, limit or seek confidential treatment for the disclosure, and (iii) discloses only the minimum amount of Confidential Information necessary for compliance.

12.4 Confidential Terms. Each Party acknowledges and agrees that this Agreement, including the terms and conditions thereof, shall be considered Confidential Information of each Party and shall be treated accordingly. Notwithstanding the foregoing, each Party acknowledges and agrees that the other may be required to disclose some or all of the information included in this Agreement in order to comply with its obligations under securities laws or the listing standards or agreements of any national or international securities exchange or The NASDAQ Stock Market, and hereby consents to such disclosure to the extent deemed advisable or appropriate by its respective counsel (but only after consulting with the other to the extent practicable). The Parties may also disclose the existence of this Agreement and terms thereof to their directors, investors, officers, employees, attorneys, accountants and other advisers on a need to know basis and may, upon obtaining a written confidentiality agreement from a Third Party or written consent from the other Party, further disclose the existence and terms of this Agreement to the Third Party to whom it may be relevant in connection with financings, acquisitions and similar transactions.

12.5 Equitable Remedies. Each Party specifically recognizes that any breach by it of this Section 12 may cause irreparable injury to the other Party and that actual damages may be difficult to ascertain, and in any event, may be inadequate. Accordingly (and without limiting the availability of legal or equitable, including injunctive, remedies under any other provisions of this Agreement), each Party agrees that in the event of any such breach, the other Party shall be entitled to seek injunctive relief and such other legal and equitable remedies as may be available.

13. TERM AND TERMINATION

13.1 Term. This Agreement shall become binding upon the Effective Date and on a country-by-country basis, shall continue thereafter in full force and effect, unless terminated sooner pursuant to this Section 13, until the expiration of the Royalty Term for such product and such country (such expiration without termination, "Expiration").

13.2 Licensee's Right to Terminate.

13.2.1 For Material Breach. Licensee may terminate this Agreement, in whole or in part, at any time if (i) Licensor materially breaches the Agreement and (ii) such material breach is not cured by Licensor within sixty (60) days after Licensee provides Licensor with written notice of such breach.

13.2.2 For Abandonment. In the event Licensee elects to abandon a Licensed Product in a particular country in the Territory in accordance with Section 7.2 above, Licensee may terminate this Agreement with respect to affected countries or products upon written notice to Licensor. In such event, all terminated rights transfer back to Licensor. Licensee will assist Licensor with the transfer of rights at Licensee's expense.

13.2.3 Without Cause. Licensee may terminate this Agreement in whole for any reason or no reason at all upon thirty (30) days prior written notice to Licensor. In such event, all terminated rights transfer back to Licensor. Licensee will assist Licensor with the transfer of rights at Licensee's expense.

13.3 Licensor's Right to Terminate.

13.3.1 For Material Breach. Licensor may terminate this Agreement with respect to affected countries and products at any time if (i) Licensee materially breaches the Agreement and (ii) such material breach is not cured by Licensee within sixty (60) days after Licensor provides Licensee with written notice of such breach.

13.3.2 For Bankruptcy, Liquidation, or Dissolution. Licensor may terminate this Agreement upon (i) the bankruptcy, liquidation or dissolution of Licensee (without further action by Licensor); or (ii) the filing of any voluntary petition for bankruptcy, dissolution, liquidation or winding-up of the affairs of Licensee which is not dismissed within one hundred twenty (120) days after the date on which it is filed or commenced.

13.3.3 For Challenge to Certain Patents. Licensor may terminate this Agreement with respect to affected countries at any time if Licensee initiates a challenge or contest to the validity of the Licensed Patent Rights or Licensor's or Biocon's rights therein before a court, any patent authority or similar forum.

13.4 Rights Upon Expiration and Termination.

13.4.1 Upon Expiration of this Agreement with respect to a Licensed Product in a country in the Territory, the licenses granted pursuant to Section 2 for such product in such country shall become perpetual, fully paid and irrevocable. Notwithstanding a termination by Licensee with respect to a Licensed Product in a country in the Territory pursuant Section 12.3.1 (Licensor uncured breach), the licenses granted pursuant to Section 2 shall, at Licensee's option, continue and, until such time as the Biocon License Agreement is terminated and this Agreement is assigned to Biocon in accordance with Section 2.4 of the Biocon License Agreement, be fully paid and royalty free.

13.4.2 Upon termination of the Biocon License Agreement for any reason other than a material breach by Biocon, the licenses granted pursuant to Section 2 shall stand automatically assigned by the Licensor to Biocon upon such termination.

13.4.3 Upon termination of this Agreement by Licensor under Section 13.3 (Licensor's Right to Terminate) or upon termination of this Agreement by Licensee pursuant to Section 13.2.2 or 13.2.3, with respect to a Licensed Product in a country in the Territory;

(a) Licensee, each Licensee Affiliate and Sublicensee shall return to Licensor the copies of and documentation and embodiments of the Apaza Know-How that Licensor provided to Licensee in accordance with Section 6.1 and that solely related to the terminated Licensed Products in the affected countries; and

(b) Licensor shall receive a perpetual, fully paid, irrevocable, and royalty-free license to use the Licensee Clinical Data solely for the purpose of Developing and Commercializing such terminated Licensed Products in the affected countries;

13.4.4 Upon Expiration or termination of this Agreement, the following Sections and Articles shall survive such expiration or termination, subject to any later termination dates provided for therein: Sections 1 (to the extent applicable), 2.2 (Sublicensing), 5 (Milestone and Royalty Reports and Accounting, with respect to any periods prior to the Expiration or termination of this Agreement), 7 (Development and Commercialization, other than Sections 7.1 and 7.2), 8 (Patent Rights), 9 (Infringement), 10 (Representations, Warranties, and Covenants), 11 (Indemnification), 12 (Confidentiality), 13 (Term and Termination), and 14 (Miscellaneous).

13.4.5 Expiration or termination of the Agreement shall not relieve the Parties of any obligation accruing before such expiration or termination. Any Expiration or early termination of this Agreement shall be without prejudice to the rights of either Party against the other accrued or accruing under this Agreement before termination.

14. MISCELLANEOUS

14.1 Independent Contractor. Neither Licensor nor Licensee, together in each case with their respective employees or representatives, are under any circumstances to be considered as employees, partners, joint venturers, agents or representatives of the other by virtue of this Agreement, and neither shall have the authority or power to bind the other or contract in the other's name.

14.2 Notices. Any notice or other communication required or permitted hereunder shall be in writing and shall be deemed given when so delivered in person, by overnight courier, by facsimile transmission (with receipt confirmed by automatic transmission report) or two (2) business days after being sent by registered or certified mail (postage prepaid, return receipt requested), as follows:

If to Licensee:

GI Therapeutics, Inc.
c/o H&M Holdings, LLC
5410 Trinity Road, Suite 400
Raleigh, NC 27612
Attention: President

With a copy to:

Hutchison PLLC
Attn: William N. Wofford
5410 Trinity Road, Suite 400
Raleigh, NC 27607
Facsimile No.: 919-829-9696

If to Licensor:

Seachaid Pharmaceuticals, Inc.
c/o Aisling Capital
888 Seventh Ave, 30th Floor
New York, NY 10106
Attention: Steve Elms
Chief Executive Officer
Telephone: (212) 652-6380
Facsimile: (212) 651-6379

With a copy to:

Seachaid Pharmaceuticals, Inc.
Attn: Radha Krishnan
801 Capitola Drive, Ste 5
Durham, NC 27713
Facsimile: (919) 354-1830

Either Party may by notice given in accordance with this Section 14.3 to the other Party designate another address or person for receipt of notices hereunder.

14.3 Binding Effect; No Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. Neither Licensor nor Licensee may assign any of its rights or delegate any of its liabilities or obligations hereunder, without the prior written consent of the other Party except that, without the prior consent of the other Party: (a) either Party may assign this Agreement in connection with the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or otherwise; and (b) either Party may assign this Agreement and/or its rights and obligations under this Agreement, in whole or in part, to any of its Affiliates. Any purported assignment or transfer in violation of this Section will be void ab initio and of no force or effect.

14.4 No Implied Waivers; Rights Cumulative. No failure on the part of Licensor or Licensee to exercise and no delay in exercising any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, including the right or power to terminate this Agreement, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor shall any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

14.5 Severability. If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement shall remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree shall remain in full force and effect to the extent not held invalid or unenforceable. The Parties further agree to replace such invalid or unenforceable provision of this Agreement with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable provision.

14.6 Force Majeure. Neither Party shall be liable for delay in delivery or nonperformance, in whole or in part, nor shall the other Party have the right to terminate this Agreement except as otherwise specifically provided in this Section 14.6, to the extent that such delay in delivery or nonperformance is caused by any event reasonably beyond the control of such Party and without the fault or negligence of such Party, including fires, floods, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorism, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any Regulatory Authority, in each case, to the extent such events are reasonably beyond the control of such Party (a "Force Majeure"); provided, however, that the Party affected by such a condition shall, within ten (10) days of its occurrence, give written notice to the other Party stating the nature of the condition, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably required and the nonperforming Party shall use its commercially reasonable efforts to remedy its inability to perform; provided, however, that in the event the suspension of performance continues for a period of ninety (90) consecutive calendar days after the date of the occurrence, and such failure to perform would constitute a material breach of this Agreement in the absence of such Force Majeure event, the nonaffected Party may terminate this Agreement immediately by written notice to the other Party.

14.7 Amendment. This Agreement may not be amended except by an instrument signed by a duly authorized representative of each of the Parties hereto.

14.8 Rules of Construction. The Parties hereto agree that they have been represented by counsel during the negotiation and execution of this Agreement and, therefore, waive the application of any law, regulation, holding or ruling of construction providing that ambiguities in an agreement or other document shall be construed against the Party drafting such agreement or document.

14.9 Expenses. Except as expressly set forth herein, each Party shall bear all fees and expenses incurred by such Party in connection with, relating to or arising out of the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby, including attorneys', accountants' and other professional fees and expenses.

14.10 Governing Law; Submission to Jurisdiction; Waiver. This Agreement shall be governed by and construed in accordance with the internal laws of the State of North Carolina without regard to its conflict of laws principles. In the event any action shall be brought to enforce or interpret the terms of this Agreement, the Parties agree that such action will be brought in the State or Federal courts located in Raleigh, North Carolina. Each of Licensor and Licensee hereby irrevocably submits with regard to any action or proceeding for itself and in respect to its property, generally and unconditionally, to the exclusive jurisdiction of the aforesaid courts. Each of Licensor and Licensee hereby irrevocably waives, and agrees not to assert, by way of motion, as a defense, counterclaim or otherwise, in any action or proceeding with respect to this Agreement: (a) any claim that it is not personally subject to the jurisdiction of the above-named courts for any reason other than the failure to lawfully serve process; (b) that it or its property is exempt or immune from jurisdiction of any such court or from any legal process commenced in such courts (whether through service of notice, attachment prior to judgment, attachment in aid of execution of judgment, execution of judgment or otherwise); and (c) to the fullest extent permitted by applicable law, that (i) the suit, action or proceeding in any such court is brought in an inconvenient forum, (ii) the venue of such suit, action or proceeding is improper, and (iii) this Agreement, or the subject matter hereof, may not be enforced in or by such courts.

14.11 Except as expressly provided in this Agreement:

14.11.1 each party specifically disclaims all representations and warranties of any kind regarding the Licensed Products or otherwise in connection with this Agreement including, without limitation, any warranties of merchantability or fitness for a particular purpose;

14.11.2 the parties make no representation or warranty regarding the suitability of any Licensed Product for Licensee's or any Third Party's requirements; and

14.11.3 the parties make no representation or warranty as to whether or not any Licensed Product infringes on the intellectual property rights of any Third Party.

14.12 Dispute Settlement. Except as otherwise expressly provided in this Section 14.11, any Dispute that the Parties cannot settle by mutual negotiations shall be resolved by binding arbitration in accordance with this Section 14.10. All disputes arising out of or in connection with the present Agreement shall be finally settled under the rules of arbitration of the American Arbitration Association by one or more arbitrators appointed in accordance with these rules. The arbitration proceedings shall be conducted in English, and in Raleigh, North Carolina. Either Party may apply to any court having jurisdiction for an order confirming, or to enforce, the decision and award of the arbitrator(s). Subject to Section 14.14, the Parties waive any right to other judicial or court action on any matter subject to arbitration hereunder, except suit to confirm or enforce the decision and award of the arbitrator(s). The arbitrator(s) shall not extend, modify or suspend any of the terms of this Agreement. A notice of, or request for, arbitration will not operate to stay, postpone or rescind the effectiveness of any demand for performance.

14.13 Entire Agreement. This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter thereof and shall supersede all previous negotiations, commitments, and writings with respect to such subject matter.

14.14 Specific Performance. Each of the Parties acknowledges and agrees that the other Party may be damaged irreparably in the event any of the provisions of the Agreement are not performed in accordance with their specific terms or otherwise are breached. Accordingly, each of the Parties agrees that the other Party shall be entitled to seek an injunction or injunctions to prevent breaches of the provisions of this Agreement and to enforce specifically this Agreement and the terms and provisions hereof in any action instituted in any court having jurisdiction over the Parties and the subject matter hereof in addition to any other remedy to which it may be entitled, at law or in equity.

14.15 Entire Agreement. This Agreement contains the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior agreements, written or oral, between the Parties with respect to the subject matter hereof.

14.16 Third Party Beneficiaries. Except as otherwise expressly set forth herein, none of the provisions of this Agreement, express or implied, is intended to be or shall be for the benefit of or enforceable by any Person (including, without limitation, any creditor of either Party hereto) other than Licensee and Licensor and their respective successors and permitted assigns. No such Person shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party hereto.

14.17 Rights in Bankruptcy. The Parties acknowledge that all rights and licenses granted under or pursuant to any Section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Code and other similar foreign laws (collectively, the "Bankruptcy Code"), licenses of rights to be "intellectual property" as defined under the Bankruptcy Code or such foreign laws. If a case is commenced during the Term by or against Licensor or its Affiliates under a Bankruptcy Code then, unless and until this Agreement is rejected as provided in such Bankruptcy Code, Licensor (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a trustee) shall perform all of the obligations provided in this Agreement to be performed by such Party. If a Bankruptcy Code case is commenced during the term by or against Licensor, this Agreement is rejected as provided in the Bankruptcy Code, and Licensee elects to retain its rights hereunder as provided in the Bankruptcy Code, then Licensor, subject to the Bankruptcy Code case (in any capacity, including debtor-in-possession) and its successors and assigns (including, without limitation, a Title 11 trustee), shall provide to Licensee copies of all information necessary for Licensee to prosecute, maintain and enjoy its license under the Licensed Technology under the terms of this Agreement held by Licensor and such successors and assigns promptly upon Licensee's written request therefor. All rights, powers and remedies of Licensee, as a licensee hereunder, provided herein are in addition to and not in substitution for any and all other rights, powers and remedies now or hereafter existing at law or in equity (including, without limitation, the Bankruptcy Code) in the event of the commencement of a Bankruptcy Code case by or against Licensor.

14.18 Counterparts; Signatures. This Agreement may be executed in multiple counterparts, all of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document. Signatures provided by facsimile or e-mail transmission shall be deemed to be original signatures.

14.19 Press Release. Neither Party shall make or publish any announcement or press release concerning the terms of this Agreement without the prior written consent of the other Party and without the prior written consent of Biocon, unless otherwise required by law.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have owed this Agreement to be executed by their duly authorized representatives, effective as of the Effective Date.

GI THERAPEUTICS, INC.

By: /s/ Jay P. Madan
Name: Jay P. Madan
Title: President

SEACHAID PHARMACEUTICALS, INC.

By: /s/ Steve Elms
Name: Steve Elms
Title: CEO and Chairman

[Signature Page to Apaza License Agreement]

Exhibit A

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

Exhibit B

[***]

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

FIRST AMENDMENT TO
APAZA LICENSE AGREEMENT

This First Amendment (this "First Amendment") to the Apaza License Agreement (the "Agreement") dated April 3, 2013, by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation, formerly GI Therapeutics, Inc., a North Carolina corporation ("Licensee"), and Seachaid Pharmaceuticals, Inc., a Delaware corporation ("Licensor"), is entered into this 8th day of June, 2015.

WHEREAS, the parties desire to amend the Agreement in order to change the terms of the Initial Payment to be made to Licensor by Licensee.

NOW THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Amendment of Section 3.1. The first sentence of Section 3.1 shall be deleted in its entirety and the following substituted in lieu thereof:

> "Licensee shall make a non-refundable payment of two hundred thousand dollars ($200,000) (the "Initial Payment") to the Licensor in three installments as follows: (i) fifty thousand dollars ($50,000) within 30 days of full execution of this agreement, (ii) twenty-five thousand dollars ($25,000) by August 31, 2015 and (iii) one hundred twenty-five thousand dollars ($125,000) upon the earlier of (a) ten (10) days following the closing of Licensee's first equity financing that brings the total equity financing raised to [***] dollars ($[***]) or (b) September 30, 2015."

2. Miscellaneous.

2.1. Defined Terms. Capitalized terms undefined herein shall have the meaning ascribed to them in the Agreement.

2.2. No Other Amendment; Effectiveness. Except as expressly amended herein, the Agreement remains in full force and effect according to its original terms.

2.3. Governing Law. This First Amendment shall be governed by and construed in accordance with the internal laws of the State of North Carolina without regard to its conflict of laws principles.

2.4. Severability. If any provision of this First Amendment is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this First Amendment shall remain in full force and effect. Any provision of this First Amendment held invalid or unenforceable only in part or degree shall remain in full force and effect to the extent not held invalid or unenforceable. The Parties further agree to replace such invalid or unenforceable provision of this First Amendment with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable provision.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

2.5. Counterparts. This First Amendment may be executed in multiple counterparts, all of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document. Signatures provided by facsimile or e-mail transmission shall be deemed to be original signatures.

IN WITNESS WHEREOF, the parties have caused this First Amendment to be executed by their duly authorized representatives as of the date first set forth above.

INNOVATE BIOPHARMACEUTICALS, INC.

By /s/ Jay P. Madan
Name: Jay P. Madan
Title: President

SEACHAID PHARMACEUTICALS, INC.

By: /s/ Steve Elms
Name: Steve Elms
Title: CEO and Chairman

SECOND AMENDMENT TO
APAZA LICENSE AGREEMENT

This Second Amendment (this "Second Amendment") to the Apaza License Agreement dated April 3, 2013, as amended by the First Amendment to Apaza License Agreement dated June 8, 2015 (the "Agreement"), by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation, formerly GI Therapeutics, Inc., a North Carolina corporation ("Licensee"), and Seachaid Pharmaceuticals, Inc., a Delaware corporation ("Licensor"), is entered into this 21st day of September, 2015.

WHEREAS, the parties desire to further amend the Agreement in order to change the terms of the Initial Payment to be made to Licensor by Licensee.

NOW THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Amendment of Section 3.1. The first sentence of Section 3.1 shall be deleted in its entirety and the following substituted in lieu thereof:

> "Licensee shall make a non-refundable payment of two hundred thousand dollars ($200,000) (the "Initial Payment") to the Licensor in four installments as follows: (i) fifty thousand dollars ($50,000) by July 8, 2015, (ii) twenty-five thousand dollars ($25,000) by August 31, 2015, (iii) twenty-five thousand dollars ($25,000) by October 31, 2015 and (iv) one hundred thousand dollars ($100,000) upon the earlier of (a) ten (10) days following the closing of Licensee's first equity financing that brings the total equity financing raised to [***] dollars ($[***]) or (b) November 30, 2015."

2. Miscellaneous.

2.1. Defined Terms. Capitalized terms undefined herein shall have the meaning ascribed to them in the Agreement.

2.2. No Other Amendment; Effectiveness. Except as expressly amended herein, the Agreement remains in full force and effect according to its original terms.

2.3 Governing Law. This Second Amendment shall be governed by and construed in accordance with the internal laws of the State of North Carolina without regard to its conflict of laws principles.

2.4. Severability. If any provision of this Second Amendment is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Second Amendment shall remain in full force and effect. Any provision of this Second Amendment held invalid or unenforceable only in part or degree shall remain in full force and effect to the extent not held invalid or unenforceable. The Parties further agree to replace such invalid or unenforceable provision of this Second Amendment with a valid and enforceable provision that shall achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable provision.

[***] Confidential treatment requested pursuant to a request for confidential treatment filed with the Securities and Exchange Commission. Omitted portions have been filed separately with the Commission.

2.5 Counterparts. This Second Amendment may be executed in multiple counterparts, all of which, when executed, shall be deemed to be an original and all of which together shall constitute one and the same document. Signatures provided by facsimile or e-mail transmission shall be deemed to be original signatures.

IN WITNESS WHEREOF, the parties have caused this Second Amendment to be executed by their duly authorized representatives as of the date first set forth above.

INNOVATE BIOPHARMACEUTICALS, INC.

By /s/ Jay P. Madan
Name: Jay P. Madan
Title: President

SEACHAID PHARMACEUTICALS, INC.

By /s/ Steve Elms
Name: Steve Elms
Title: CEO and Chairman

Exhibit 10.11

INNOVATE BIOPHARMACEUTICALS INC.

2015 STOCK INCENTIVE PLAN

1. Purpose

The purpose of this 2015 Stock Incentive Plan (the "**Plan**") of Innovate Biopharmaceuticals Inc.**,** a Delaware corporation (the "**Company**"), is to advance the interests of the Company's stockholders by enhancing the Company's ability to attract, retain and motivate persons who are expected to make important contributions to the Company and by providing such persons with equity ownership opportunities and performance-based incentives that are intended to align their interests with those of the Company's stockholders. Except where the context otherwise requires, the term "**Company**" includes the Company's present or future parent or subsidiary corporations as defined in Sections 424(e) or (f) of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "**Code**") and other business ventures (including, without limitation, any joint venture or limited liability company) in which the Company has a controlling interest, as determined by the Board of Directors of the Company (the "**Board**").

2. Eligibility

All of the Company's employees, officers, directors, and individual consultants and advisors (each a "**Service Provider**") are eligible to receive options, restricted stock, restricted stock units and other stock-based awards (each, an "**Award**") under the Plan. Each person who receives an Award under the Plan is deemed a "**Participant**."

3. Administration and Delegation

(a) Administration by Board of Directors. The Plan shall be administered by the Board. The Board shall have authority to grant Awards and to adopt, amend and repeal such administrative rules, guidelines and practices relating to the Plan as it shall deem advisable. The Board may correct any defect, supply any omission or reconcile any inconsistency in the Plan or any Award in the manner and to the extent it shall deem expedient to carry the Plan into effect and it shall be the sole and final judge of such expediency. All decisions by the Board shall be made in the Board's sole discretion and shall be final and binding on all persons having or claiming any interest in the Plan or in any Award. No director or person acting pursuant to the authority delegated by the Board shall be liable for any action or determination relating to or under the Plan made in good faith.

(b) Appointment of Committees. To the extent permitted by applicable law, the Board may delegate any or all of its powers under the Plan to one or more committees or subcommittees of the Board (a "**Committee**"). All references in the Plan to the "**Board**" shall mean the Board or a Committee of the Board to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.

4. Stock Available for Awards.

(a) Subject to adjustment under Section 8, Awards may be made under the Plan for up to 3,600,000 shares of the common stock of the Company (the "**Common Stock**"). If any Award expires or is terminated, surrendered or canceled without having been fully exercised or is forfeited in whole or in part (including as the result of shares of Common Stock subject to such Award being repurchased by the Company at the original issuance price pursuant to a contractual repurchase right) or results in any Common Stock not being issued, the unused Common Stock covered by such Award shall again be available for the grant of Awards under the Plan. Further, shares of Common Stock tendered to the Company by a Participant to exercise an Award shall be added to the number of shares of Common Stock available for the grant of Awards under the Plan. However, in the case of Incentive Stock Options (as hereinafter defined), the foregoing provisions shall be subject to any limitations under the Code. Shares issued under the Plan may consist in whole or in part of authorized but unissued shares or treasury shares.

(b) Substitute Awards. In connection with a merger or consolidation of an entity with the Company or the acquisition by the Company of property or stock of an entity, the Board may grant Awards in substitution for any options or other stock or stock-based awards granted by such entity or an affiliate thereof. Substitute Awards may be granted on such terms as the Board deems appropriate in the circumstances, notwithstanding any limitations on Awards contained in the Plan. Substitute Awards shall not count against the overall share limit set forth in Section 4(a), except as may be required by reason of Section 422 and related provisions of the Code.

5. Stock Options

(a) General. The Board may grant options to purchase Common Stock (each, an "**Option**") and determine the number of shares of Common Stock to be covered by each Option, the exercise price of each Option and the conditions and limitations applicable to the exercise of each Option, including conditions relating to applicable federal or state securities laws, as it considers necessary or advisable. An Option, or portion of an Option, which is not intended to be or fails to qualify as an Incentive Stock Option (as hereinafter defined) shall be designated a "**Nonstatutory Stock Option.**"

(b) Incentive Stock Options. An Option that the Board intends to be an "incentive stock option" as defined in Section 422 of the Code (an "**Incentive Stock Option**") shall only be granted to employees of the Company and any other entities the employees of which are eligible to receive Incentive Stock Options under the Code, and shall be subject to and shall be construed consistently with the requirements of Section 422 of the Code. A Participant who owns more than 10% of the total combined voting power of all classes of outstanding stock of the Company shall not be eligible for the grant of an Incentive Stock Option unless (i) the exercise price is at least 110% of the Fair Market Value (as defined below) on the date the Option is granted and (ii) such Incentive Stock Option by its terms is not exercisable after the expiration of five years from the date the Option is granted. The Company shall have no liability to a Participant, or any other party, if an Option (or any part thereof) that is intended to be an Incentive Stock Option is not an Incentive Stock Option or for any action taken by the Board pursuant to Section 9(g), including without limitation the conversion of an Incentive Stock Option to a Nonstatutory Stock Option.

(c) Exercise Price. The Board shall establish the exercise price of each Option and specify such exercise price in the applicable option agreement. The exercise price shall be not less than 100% of the Fair Market Value on the date the Option is granted unless the Board specifically determines that the exercise price is intended to be less than such Fair Market Value, in which case the option agreement shall contain provisions complying with Section 409A of the Code; provided that if the Board approves the grant of an Option with an exercise price to be determined on a future date, the exercise price shall be not less than 100% of the Fair Market Value on such future date. The term "**Fair Market Value**" shall mean, as of a given date: (i) if the Common Stock is listed on a national securities exchange, the last sale price of the Common Stock in the principal trading market for the Common Stock on such date; (ii) if the Common Stock is not listed on a national securities exchange, but is traded in the over-the counter market, the closing bid price for the Common Stock on such date, as reported by the OTC Bulletin Board or the National Quotation Bureau, Incorporated or similar publisher of such quotations; or (iii) if the Common Stock is not listed on a national securities exchange or traded in the over-the-counter market, such price as shall be determined by (or in a manner approved by) the Board in good faith and in compliance with applicable provisions of the Code and the regulations issued thereunder.

(d) Duration of Options. Each Option shall be exercisable at such times and subject to such terms and conditions as the Board may specify in the applicable option agreement.

(e) Exercise of Option. Options may be exercised by delivery to the Company of a written notice of exercise signed by the proper person or by any other form of notice (including electronic notice) approved by the Board together with payment in full as specified in Section 5(f) for the number of shares of Common Stock for which the Option is exercised. Shares of Common Stock subject to the Option will be delivered by the Company following exercise either as soon as practicable or, subject to such conditions as the Board shall specify, on a deferred basis (with the Company's obligation to be evidenced by an instrument providing for future delivery of the deferred shares at the time or times specified by the Board).

(f) Payment Upon Exercise. Common Stock purchased upon the exercise of an Option granted under the Plan shall be paid for as follows:

(1) in cash or by check, payable to the order of the Company;

(2) except as may otherwise be provided in the applicable option agreement, by (i) delivery of an irrevocable and unconditional undertaking by a creditworthy broker to deliver promptly to the Company sufficient funds to pay the exercise price and any required tax withholding or (ii) delivery by the Participant to the Company of a copy of irrevocable and unconditional instructions to a creditworthy broker to deliver promptly to the Company cash or a check sufficient to pay the exercise price and any required tax withholding;

(3) when the Common Stock is registered under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**") and to the extent provided for in the applicable option agreement or approved by the Board, in its sole discretion, by delivery (either by actual delivery or attestation) of shares of Common Stock owned by the Participant valued at their Fair Market Value, provided (i) such method of payment is then permitted under applicable law, (ii) such Common Stock, if acquired directly from the Company, was owned by the Participant for such minimum period of time, if any, as may be established by the Board in its discretion and (iii) such Common Stock is not subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements;

(4) to the extent permitted by applicable law and provided for in the applicable option agreement or approved by the Board, in its sole discretion, by (i) delivery of a promissory note of the Participant to the Company on terms determined by the Board, or (ii) payment of such other lawful consideration as the Board may determine; or

(5) by any combination of the above permitted forms of payment.

6. Restricted Stock; Restricted Stock Units

(a) General. The Board may grant Awards entitling recipients to acquire shares of Common Stock ("**Restricted Stock**"), subject to the right of the Company to repurchase all or part of such shares at their issue price or other stated or formula price (or to require forfeiture of such shares if issued at no cost) from the recipient in the event that conditions specified by the Board in the applicable Award are not satisfied prior to the end of the applicable restriction period or periods established by the Board for such Award. Instead of granting Awards for Restricted Stock, the Board may grant Awards entitling the recipient to receive shares of Common Stock to be delivered at the time such shares of Common Stock vest ("**Restricted Stock Units**") (Restricted Stock and Restricted Stock Units are each referred to herein as a "**Restricted Stock Award**").

(b) Terms and Conditions. The Board shall determine the terms and conditions of a Restricted Stock Award, including the conditions for repurchase (or forfeiture) and the issue price, if any.

(c) Additional Provisions Relating to Restricted Stock.

(1) Dividends. Participants holding shares of Restricted Stock will be entitled to all ordinary cash dividends paid with respect to such shares, unless otherwise provided by the Board. If any such dividends or distributions are paid in shares, or consist of a dividend or distribution to holders of Common Stock other than an ordinary cash dividend, the shares, cash or other property will be subject to the same restrictions on transferability and forfeitability as the shares of Restricted Stock with respect to which they were paid. Each dividend payment will be made no later than the end of the calendar year in which the dividends are paid to stockholders of that class of stock or, if later, the 15th day of the third month following the date the dividends are paid to stockholders of that class of stock.

(2) Stock Certificates. The Company may require that any stock certificates issued in respect of a Restricted Stock Award shall be registered in the name of the Participant and be deposited by the Participant, together with a stock power endorsed in blank, with the Company (or its designee). After the expiration of the applicable restriction periods, upon request of a Participant or as otherwise determined by the Company, the Company (or such designee) shall deliver the certificates no longer subject to such restrictions to the Participant or if the Participant has died, to the beneficiary designated, in a manner determined by the Board, by a Participant to receive amounts due or exercise rights of the Participant in the event of the Participant's death (the "**Designated Beneficiary**"). In the absence of an effective designation by a Participant, "Designated Beneficiary" shall mean the Participant's then living spouse, or, if none, the Participant's estate.

7. Other Stock-Based Awards

Other Awards of shares of Common Stock, and other Awards that are valued in whole or in part by reference to, or are otherwise based on, shares of Common Stock or other property, may be granted hereunder to Participants ("**Other Stock-Based Awards**"), including without limitation stock appreciation rights and Awards entitling recipients to receive shares of Common Stock to be delivered in the future. Such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan or as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock-Based Awards may be paid in shares of Common Stock or cash, as the Board shall determine. Subject to the provisions of the Plan, the Board shall determine the conditions of each Other Stock-Based Award, including any purchase price applicable thereto.

8. Adjustments for Changes in Common Stock and Certain Other Events

(a) Changes in Capitalization. In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of Common Stock other than an ordinary cash dividend, (i) the number and class of securities available under this Plan, (ii) the number and class of securities and exercise price per share of each outstanding Option, (iii) the number of shares subject to and the repurchase price per share subject to each outstanding Restricted Stock Award, and (iv) the terms of each other outstanding Award shall be equitably adjusted by the Company (or substituted Awards may be made, if applicable) in the manner determined by the Board. Without limiting the generality of the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend and the exercise price of and the number of shares subject to an outstanding Option are adjusted as of the date of the distribution of the dividend (rather than as of the record date for such dividend), then an optionee who exercises an Option between the record date and the distribution date for such stock dividend shall be entitled to receive, on the distribution date, the stock dividend with respect to the shares of Common Stock acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend.

(b) Change in Control

(1) Definition. Unless otherwise specifically provided in an Award agreement, a "**Change in Control**" shall be deemed to have occurred upon the first to occur of:

(i) any "person" (as such term is used in sections 13(d) and 14(d) of the Exchange Act) becoming a "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of securities of the Company representing either (A) more than a majority of the voting power of the then outstanding securities of the Company, or (B) more than a majority of the aggregate fair market value of the then outstanding securities of the Company; provided, however, that a Change in Control shall not be deemed to occur as a result of (x) a transaction in which the Company becomes a subsidiary of another corporation and in which the stockholders of the Company, immediately prior to the transaction, will beneficially own, immediately after the transaction, shares entitling such stockholders to more than majority of all votes to which all stockholders of the parent corporation would be entitled in the election of directors, or (y) a transaction in which the person acquires newly issued securities of the Company in exchange for an investment in the Company; or

(ii) the consummation of either: (A) a merger, share exchange, consolidation or reorganization of the Company where the stockholders of the Company, immediately prior to the merger or consolidation, will not beneficially own, immediately after the merger, share exchange, consolidation or reorganization, shares entitling such stockholders to either (x) more than a majority of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors, or (y) more than a majority of the aggregate fair market value of then outstanding securities of the Company; or (B) a sale or other disposition of all or substantially all of the assets of the Company.

(2) Consequences of a Change in Control on Awards Other than Restricted Stock Awards. In connection with a Change in Control, the Board may take any one or more of the following actions as to all (or any portion of) outstanding Awards other than Restricted Stock Awards on such terms as the Board determines: (i) provide that Awards shall be assumed, or substantially equivalent Awards shall be substituted, by the acquiring or succeeding corporation (or an affiliate thereof) in compliance with the applicable provisions of the Code, including Code Sections 409A, 422 and 424, (ii) upon written notice to a Participant, provide that the Participant's unexercised Options or other unexercised Awards will terminate immediately prior to the consummation of such Change in Control unless exercised by the Participant within a specified period following the date of such notice, (iii) provide that outstanding Awards shall become exercisable, realizable or deliverable, or restrictions applicable to an Award shall lapse, in whole or in part prior to or upon such Change in Control, (iv) in the event of a Change in Control under the terms of which holders of Common Stock will receive upon consummation thereof a cash payment for each share surrendered in the Change in Control (the "**Acquisition Price**"), make or provide for a cash payment to a Participant equal to the excess, if any, of (A) the Acquisition Price times the number of shares of Common Stock subject to the Participant's Options or other Awards (to the extent the exercise price does not exceed the Acquisition Price) less (B) the aggregate exercise price of all such outstanding Options or other Awards and any applicable tax withholdings, in exchange for the termination of such Options or other Awards, (v) provide that, in connection with a liquidation or dissolution of the Company, Awards shall convert into the right to receive liquidation proceeds (if applicable, net of the exercise price thereof) and (vi) any combination of the foregoing. In taking any of the actions permitted under this Section 8(b), the Board shall not be obligated by the Plan to treat all Awards, or all Awards of the same type, identically.

For purposes of clause (i) above, an Option shall be considered assumed if, following consummation of the Change in Control, the Option confers the right to purchase, for each share of Common Stock subject to the Option immediately prior to the consummation of the Change in Control, the consideration (whether cash, securities or other property) received as a result of the Change in Control by holders of Common Stock for each share of Common Stock held immediately prior to the consummation of the Change in Control (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares of Common Stock); provided, however, that if the consideration received as a result of the Change in Control is not solely common stock of the acquiring or succeeding corporation (or an affiliate thereof), the Company may, with the consent of the acquiring or succeeding corporation, provide for the consideration to be received upon the exercise of Options to consist solely of common stock of the acquiring or succeeding corporation (or an affiliate thereof) with equivalent in value (as determined by the Board) to the per share consideration received by holders of outstanding shares of Common Stock as a result of the Change in Control.

(3) Consequences of a Change in Control on Restricted Stock Awards. Upon the occurrence of a Change in Control other than a liquidation or dissolution of the Company, the repurchase and other rights of the Company under each outstanding Restricted Stock Award shall inure to the benefit of the Company's successor and shall, unless the Board determines otherwise, apply to the cash, securities or other property which the Common Stock was converted into or exchanged for pursuant to such Change in Control in the same manner and to the same extent as they applied to the Common Stock subject to such Restricted Stock Award. Upon the occurrence of a Change in Control involving the liquidation or dissolution of the Company, except to the extent specifically provided to the contrary in the instrument evidencing any Restricted Stock Award or any other agreement between a Participant and the Company, all restrictions and conditions on all Restricted Stock Awards then outstanding shall automatically be deemed terminated or satisfied.

9. General Provisions Applicable to Awards

(a) Transferability of Awards. Except as the Board may otherwise expressly determine or provide in an Award, Awards shall not be sold, assigned, transferred, pledged or otherwise encumbered by the person to whom they are granted, either voluntarily or by operation of law, except by will or the laws of descent and distribution or, other than in the case of an Incentive Stock Option, pursuant to a qualified domestic relations order, and, during the life of the Participant, shall be exercisable only by the Participant. References to a Participant, to the extent relevant in the context, shall include references to authorized transferees.

(b) Documentation. Unless otherwise expressly determined by the Board, each Incentive Stock Option shall be evidenced by a Notice of Incentive Stock Option and Incentive Stock Option Agreement substantially in the form attached as **Exhibit A**, each Nonstatutory Stock Option shall be evidenced by a Notice of Nonstatutory Stock Option and Nonstatutory Stock Option Agreement substantially in the form attached as **Exhibit B**, and each Restricted Stock Award shall be evidenced by a Summary of Restricted Stock Purchase and Restricted Stock Purchase Agreement substantially in the form attached as **Exhibit C**. Each Award may contain terms and conditions in addition to those set forth in the Plan.

(c) Board Discretion. Except as otherwise provided by the Plan, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award need not be identical, and the Board need not treat Participants uniformly.

(d) Termination of Status. The Board shall determine the effect on an Award of the disability, death, termination of employment, authorized leave of absence or other change in the employment or other status of a Participant and the extent to which, and the period during which, the Participant, or the Participant's legal representative, conservator, guardian or Designated Beneficiary, may exercise rights under the Award.

(e) Withholding. The Participant must satisfy all applicable federal, state, and local or other income and employment tax withholding obligations before the Company will deliver stock certificates or otherwise recognize ownership of Common Stock under an Award. The Company may decide to satisfy the withholding obligations through additional withholding on salary or wages. If the Company elects not to or cannot withhold from other compensation, the Participant must pay the Company the full amount, if any, required for withholding or have a broker tender to the Company cash equal to the withholding obligations. Payment of withholding obligations is due before the Company will issue any shares on exercise or release from forfeiture of an Award or, if the Company so requires, at the same time as is payment of the exercise price unless the Company determines otherwise. If provided for in an Award or approved by the Board in its sole discretion, a Participant may satisfy such tax obligations in whole or in part by delivery of shares of Common Stock, including shares retained from the Award creating the tax obligation, valued at their Fair Market Value; provided, however, except as otherwise provided by the Board, that the total tax withholding where stock is being used to satisfy such tax obligations cannot exceed the Company's minimum statutory withholding obligations (based on minimum statutory withholding rates for federal and state tax purposes, including payroll taxes, that are applicable to such supplemental taxable income). Shares surrendered to satisfy tax withholding requirements cannot be subject to any repurchase, forfeiture, unfulfilled vesting or other similar requirements.

(f) Amendment of Award.

(1) The Board may amend, modify or terminate any outstanding Award, including but not limited to, substituting therefor another Award of the same or a different type, changing the date of exercise or realization, and converting an Incentive Stock Option to a Nonstatutory Stock Option, provided that the Participant's consent to such action shall be required unless the Board determines that the action, taking into account any related action, would not materially and adversely affect the Participant.

(2) The Board may, without stockholder approval, amend any outstanding Award granted under the Plan to provide an exercise price per share that is lower than the then-current exercise price per share of such outstanding Award provided that such amended exercise price is at least equal to the then-current Fair Market Value. The Board may also, without stockholder approval, cancel any outstanding award (whether or not granted under the Plan) and grant in substitution new Awards under the Plan covering the same or a different number of shares of Common Stock and having an exercise price per share lower than the then-current exercise price per share of the cancelled award.

(g) Conditions on Delivery of Stock. The Company will not be obligated to deliver any shares of Common Stock pursuant to the Plan or to remove restrictions from shares previously delivered under the Plan until (i) all conditions of the Award have been met or removed to the satisfaction of the Company, (ii) in the opinion of the Company's counsel, all other legal matters in connection with the issuance and delivery of such shares have been satisfied, including any applicable securities laws and any applicable stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Company may consider appropriate to satisfy the requirements of any applicable laws, rules, regulations or contracts of the Company.

(h) Acceleration. The Board may at any time provide that any Award shall become immediately exercisable in full or in part, free of some or all restrictions or conditions, or otherwise realizable in full or in part, as the case may be.

10. Miscellaneous

(a) No Right To Employment or Other Status. No person shall have any claim or right to be granted an Award, and the grant of an Award shall not be construed as giving a Participant the right to continued employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan, except as expressly provided in the applicable Award.

(b) No Rights As Stockholder. Subject to the provisions of the applicable Award, no Participant or Designated Beneficiary shall have any rights as a stockholder with respect to any shares of Common Stock to be distributed with respect to an Award until becoming the record holder of such shares. Notwithstanding the foregoing, in the event the Company effects a split of the Common Stock by means of a stock dividend or otherwise and the exercise price of and the number of shares subject to such Option are adjusted as of the effective date of the stock dividend or split (rather than as of the record date for such stock dividend or split), then an optionee who exercises an Option between the record date and the distribution date for such stock dividend or split shall be entitled to receive, on the distribution date, the stock dividend or split with respect to the shares of Common Stock acquired upon such Option exercise, notwithstanding the fact that such shares were not outstanding as of the close of business on the record date for such stock dividend or split.

(c) Effective Date and Term of Plan. The Plan shall become effective on the date on which it is adopted by the Board. No Awards shall be granted under the Plan after the expiration of 10 years from the earlier of (i) the date on which the Plan was adopted by the Board or (ii) the date the Plan was approved by the Company's stockholders, but Awards previously granted may extend beyond that date.

(d) Amendment of Plan. The Board may amend, suspend or terminate the Plan or any portion thereof at any time; provided, however, that if at any time the approval of the Company's stockholders is required as to any modification or amendment under Section 422 of the Code or any successor provision with respect to Incentive Stock Options, the Board may not effect such modification or amendment without such approval. Unless otherwise specified in the amendment, any amendment to the Plan adopted in accordance with this Section 10(d) shall apply to, and be binding on the holders of, all Awards outstanding under the Plan at the time the amendment is adopted, provided the Board determines that such amendment does not materially and adversely affect the rights of Participants under the Plan.

(e) Authorization of Sub-Plans. The Board may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable blue sky, securities or tax laws of various jurisdictions. The Board shall establish such sub-plans by adopting supplements to this Plan containing (i) such limitations on the Board's discretion under the Plan as the Board deems necessary or desirable or (ii) such additional terms and conditions not otherwise inconsistent with the Plan as the Board shall deem necessary or desirable. All supplements adopted by the Board shall be deemed to be part of the Plan, but each supplement shall apply only to Participants within the affected jurisdiction and the Company shall not be required to provide copies of any supplement to Participants in any jurisdiction which is not the subject of such supplement.

(f) Non-Plan Equity-Based Awards. Nothing in this Plan is intended to, or shall, impair or affect the Board's ability to make non-Plan equity-based awards.

(g) Compliance with Code Section 409A. It is intended that all Awards granted hereunder be either exempt from, or issued in compliance with, Code Section 409A. The Company shall have no liability to a Participant, or any other party, if an Award that is intended to be exempt from, or compliant with, Code Section 409A is not so exempt or compliant, or for any action taken by the Board.

(h) Governing Law. The provisions of the Plan and all Awards made hereunder shall be governed by and construed in accordance with the General Corporation Law of the State of Delaware, as to matters within the scope thereof, and the internal laws of the State of North Carolina (without reference to conflict of law provisions), as to all other matters.

* * * * * * * *

INNOVATE BIOPHARMACEUTICALS INC.

2015 STOCK INCENTIVE PLAN

CALIFORNIA SUPPLEMENT

Pursuant to Section 10(e) of the Plan, the Board has adopted this supplement for purposes of satisfying the requirements of Section 25102(o) of the California Corporations Code, as amended:

Any Awards granted under the Plan to a Participant who is a resident of the State of California on the date of grant (a "**California Participant**") shall be subject to the following additional limitations, terms and conditions:

1. Additional Limitations on Awards.

(a) Generally. The terms of all Awards granted to a California Participant under Sections 5, 6 or 7 of the Plan shall comply, to the extent applicable, with Section 260.140.41 or Section 260.140.42 of the California Regulations.

(b) Maximum Duration of Options. No Options granted to California Participants shall have a term in excess of 10 years measured from the Option grant date.

(c) Minimum Exercise Period Following Termination. Unless a California Participant's employment is terminated for cause (as defined by applicable law, the terms of any contract of employment between the Company and such Participant, or in the instrument evidencing the grant of such Participant's Option), in the event of termination of employment of such Participant, such Participant shall have the right to exercise an Option, to the extent that he or she was otherwise entitled to exercise such Option on the date employment terminated, until the earlier of the Option expiration date or: (i) at least six months from the date of termination, if termination was caused by such Participant's death or "**permanent and total disability**" (within the meaning of Section 22(e)(3) of the Code) and (ii) at least 30 days from the date of termination, if termination was caused other than by such Participant's death or "permanent and total disability" (within the meaning of Section 22(e)(3) of the Code).

2. Additional Requirement to Provide Information to California Participants. Unless the Plan or agreement complies with all conditions of Rule 701 of the Securities Act of 1933, as amended ("**Rule 701**"), the Company shall provide to each California Participant and to each California Participant who acquires Common Stock pursuant to the Plan, not less frequently than annually, copies of annual financial statements (which need not be audited). The Company shall not be required to provide such statements to key employees whose duties in connection with the Company assure their access to equivalent information or when the Plan or agreement complies with all conditions of Rule 701.

3. Additional Limitations on Timing of Awards. No Award granted to a California Participant shall become exercisable, vested or realizable, as applicable to such Award, unless the Plan has been approved by the holders of at least a majority of the Company's outstanding voting securities by the later of (i) within 12 months before or after the date the Plan was adopted by the Board or the agreement entered into; and (ii) prior to or within 12 months of the granting of any option or issuance of any security under the Plan or agreement to a California Participant.

4. Additional Restriction Regarding Recapitalizations, Stock Splits, Etc. For purposes of Section 8 of the Plan, in the event of a stock split, reverse stock split, stock dividend, recapitalization, combination, reclassification or other distribution of the Company's securities, the number of securities allocated to each California Participant must be adjusted proportionately and without the receipt by the Company of any consideration from any California Participant.

EXHIBIT A

Notice of Incentive Stock Option
and
Incentive Stock Option Agreement

[Filed as Exhibit 10.12 to the Form 10-K for the year ended December 31, 2017]

EXHIBIT B

Notice of Nonstatutory Stock Option
and
Nonstatutory Stock Option Agreement

[Filed as Exhibit 10.13 to the Form 10-K for the year ended December 31, 2017]

EXHIBIT C

Summary of Restricted Stock Purchase and Restricted Stock Purchase Agreement

[Filed as Exhibit 10.14 to the Form 10-K for the year ended December 31, 2017]

FIRST AMENDMENT TO THE
INNOVATE BIOPHARMACEUTICALS INC.
2015 STOCK INCENTIVE PLAN

February 2, 2016

THIS FIRST AMENDMENT to the Innovate Biopharmaceuticals Inc. 2015 Stock Incentive Plan (the "**Plan**") is effective as of the date set forth above.

WHEREAS, the Board of Directors (the "**Board**") of Innovate Biopharmaceuticals Inc., a Delaware corporation (the "**Company**"), has adopted and the stockholders of the Company have approved the Plan; and

WHEREAS, the Board and the requisite stockholders of the Company have approved this amendment of the Plan in order to increase the number of shares of Common Stock authorized for issuance under the Plan by 1,400,000 shares, from 3,600,000 shares to 5,000,000 shares.

NOW, THEREFORE, the Plan shall be amended as follows:

1. The first sentence of Paragraph 4(a) of the Plan shall be deleted in its entirety and the following substituted in lieu thereof:

"(a) Subject to adjustment under Section 8, Awards may be made under the Plan for up to 5,000,000 shares of the common stock of the Company (the "**Common Stock**")."

2. Except as amended herein, the terms and provisions of the Plan shall remain unchanged and in full force and effect.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the undersigned has executed this First Amendment to the Innovate Biopharmaceuticals Inc. 2015 Stock Incentive Plan as of the date set forth above.

INNOVATE BIOPHARMACEUTICALS INC.

By: /s/ Jay P. Madan
Jay P. Madan, President

SECOND AMENDMENT TO THE
INNOVATE BIOPHARMACEUTICALS INC.
2015 STOCK INCENTIVE PLAN

February 22, 2017

THIS SECOND AMENDMENT to the Innovate Biopharmaceuticals Inc. 2015 Stock Incentive Plan (the "**Plan**") is effective as of the date set forth above.

WHEREAS, the Board of Directors (the "**Board**") of Innovate Biopharmaceuticals Inc., a Delaware corporation (the "**Company**"), has adopted and the stockholders of the Company have approved the Plan; and

WHEREAS, the Board and the requisite stockholders of the Company have approved this amendment of the Plan in order to (i) increase the number of shares of Common Stock authorized for issuance under the Plan by 5,000,000 shares, from 15,000,000 shares to 20,000,000 shares, (ii) allow the Company to make awards to entities under the Plan and (iii) clarify that a reverse merger transaction does not constitute a "Change in Control" for purposes of the Plan.

NOW, THEREFORE, the Plan shall be amended as follows:

1. The first sentence of Paragraph 4(a) of the Plan shall be deleted in its entirety and the following substituted in lieu thereof:

"(a) Subject to adjustment under Section 8, Awards may be made under the Plan for up to 20,000,000 shares of the common stock of the Company (the "**Common Stock**")."

2. The first sentence of Paragraph 2 of the Plan shall be deleted in its entirety and the following substituted in lieu thereof:

"All of the Company's employees, officers, directors, and consultants and advisors (each a "**Service Provider**") are eligible to receive options, restricted stock, restricted stock units and other stock-based awards (each, an "**Award**") under the Plan."

3. The following sentence shall be added to the end of Paragraph 8(b)(1) of the Plan:

"For purposes of clarity, a reverse merger transaction in which the Company merges into another entity and the stockholders of the Company immediately prior to such merger will beneficially own, immediately after the merger, shares entitling such stockholders to a majority of all votes to which all stockholders of the surviving corporation would be entitled in the election of directors does not constitute a Change in Control.

4. Except as amended herein, the terms and provisions of the Plan shall remain unchanged and in full force and effect.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the undersigned has executed this Second Amendment to the Innovate Biopharmaceuticals Inc. 2015 Stock Incentive Plan as of the date set forth above.

INNOVATE BIOPHARMACEUTICALS INC.

By: /s/ Jay P. Madan
Jay P. Madan, President

Exhibit 10.12

INNOVATE BIOPHARMACEUTICALS INC.

NOTICE OF INCENTIVE STOCK OPTION
2015 STOCK INCENTIVE PLAN

Innovate Biopharmaceuticals Inc., a Delaware corporation (the "**Company**") grants to the undersigned (the "**Participant**") the following incentive stock option to purchase shares (the "**Shares**") of the common stock of the Company (the "**Common Stock**"), pursuant to the Company's 2015 Stock Incentive Plan (the "**Plan**"):

Participant:	***[**Participant Name**]**
Total Number of Shares:	***[**Number of Shares**]**
Grant Date:	***[**Grant Date**]**
Exercise Price per Share:	$****[**Exercise Price**]**
Vesting Commencement Date:	***[**Vesting Date**]**
Vesting Schedule:	***[**Vesting Schedule]
	***[**In addition, this Option may vest and become exercisable on an accelerated basis under Section 2 of the Incentive Stock Option Agreement.**]**
Final Exercise Date:	***[**Expiration Date**]** This Option may expire earlier pursuant to Section 3 of the Incentive Stock Option Agreement if the Participant's relationship with the Company is terminated or pursuant to Section 8 of the Plan.

This incentive stock option is granted under and governed by the terms and conditions of the Plan and the Incentive Stock Option Agreement, both of which are incorporated herein by reference. By signing below, the Participant accepts this incentive stock option, acknowledges receipt of a copy of the Plan and the Incentive Stock Option Agreement, and agrees to the terms thereof.

***[PARTICIPANT NAME]:**

_____
(Signature)

Address: _____

_____

INNOVATE BIOPHARMACEUTICALS INC.:

By: _____

Name: _____

Title: _____

Date: _____

THE OPTION GRANTED PURSUANT TO THIS AGREEMENT AND THE SHARES ISSUABLE UPON THE EXERCISE THEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY STATE SECURITIES LAWS, AND MAY NOT BE SOLD, PLEDGED OR OTHERWISE TRANSFERRED WITHOUT AN EFFECTIVE REGISTRATION THEREOF UNDER SUCH ACT OR APPLICABLE LAWS OR AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY AND ITS COUNSEL THAT SUCH REGISTRATION IS NOT REQUIRED.

INNOVATE BIOPHARMACEUTICALS INC.

INCENTIVE STOCK OPTION AGREEMENT
Granted under 2015 Stock Incentive Plan

1. Grant of Option.

This Incentive Stock Option Agreement (the "**Agreement**") evidences the grant by Innovate Biopharmaceuticals Inc., a Delaware corporation (the "**Company**"), on the Grant Date to the Participant, an employee of the Company, of an option (this "**Option**") to purchase, in whole or in part, on the terms provided herein and in the Plan, the Total Number of Shares at the Exercise Price per Share, all as defined and set forth in the accompanying Notice of Incentive Stock Option (the "**Notice**"). Capitalized terms that are not otherwise defined herein or in the Notice shall have the meanings given to such terms in the Plan.

It is intended that this Option shall be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "**Code**"). If for any reason the Option, or any portion thereof, does not meet the requirements of Section 422 of the Code, then the Option, or any portion thereof, as necessary, shall be deemed a nonstatutory stock option granted under the Plan. Except as otherwise indicated by the context, the term "Participant," as used in this Agreement, shall include any person who acquires the right to exercise this Option validly under its terms.

2. Vesting Schedule.

This Option shall vest and become exercisable at the time or times set forth in the accompanying Notice. **[**In addition, this Option may vest and become exercisable on an accelerated basis as follows:]

***[**Insert any applicable acceleration provisions**]**

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this Option shall be in writing in substantially the form of the Notice of Stock Option Exercise attached to this Agreement as **Exhibit A**, signed by the Participant, and received by the Company at its principal office, accompanied by this Agreement, and payment in full in the manner provided in the Plan. The Participant may purchase less than the number of Shares subject to this Option; provided that, no partial exercise of this Option may be for any fractional share.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this Option may not be exercised unless the Participant, at the time of the exercise of this Option, is, and has been at all times since the Grant Date, a Service Provider to or of the Company or any subsidiary of the Company as defined in Section 424 (f) of the Code (an "**Eligible Participant**").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this Option shall terminate three months after such cessation (but in no event after the Final Exercise Date); provided that, this Option shall be exercisable only to the extent that the Participant was entitled to exercise this Option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the non-competition or confidentiality provisions of any employment agreement, confidentiality and nondisclosure agreement, or other agreement between the Participant and the Company, the right to exercise this Option shall terminate immediately upon such violation.

(d) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while the Participant is an Eligible Participant and the Company has not terminated such relationship for "Cause" (as defined below), this Option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee); provided that, this Option shall be exercisable only to the extent that this Option was exercisable by the Participant on the date of the Participant's death or disability, and further provided that this Option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's status as a Service Provider is terminated by the Company for Cause (as defined below), the right to exercise this Option shall terminate immediately upon the effective date of such termination. If the Participant is party to an agreement with the Company that contains an applicable definition of "cause", "**Cause**" shall have the meaning ascribed to such term in such agreement. Otherwise, "**Cause**" shall mean willful misconduct by the Participant or willful failure by the Participant to perform the Participant's responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been discharged for Cause if the Company determines, within 30 days after the Participant's resignation, that discharge for cause was warranted.

4. Restrictions on Transfer; Rights of First Refusal and Stockholder Agreements.

(a) Bylaws. The Participant acknowledges and agrees that the Shares are subject to the provisions of the Company's Bylaws, as amended from time to time (the "**Bylaws**"), including without limitation, all restrictions on transfer and rights of first refusal described in the Bylaws. The Participant may inspect the Bylaws at the Company's principal office.

(b) Legend. Any certificate representing Shares shall bear a legend substantially in the following form (in addition to, or in combination with, any legend required by applicable federal and state securities laws and agreements relating to the transfer and/or voting of the Company's securities):

> "The securities represented by this certificate, and the transfer thereof, are subject to the restriction on transfer provisions of the Bylaws of the Company, a copy of which is on file in, and may be examined at, the principal office of the Company."

(c) Stockholder Agreements. The Participant acknowledges and agrees that the Company may condition the issuance of the Shares upon the Participant joining and becoming a party to such stockholder agreements, which may impose certain contractual rights and obligations on the Shares, as may be entered into from time to time by and among the Company and certain holders of the Company's capital stock.

5. Agreement in Connection with Public Offering. The Participant agrees, in connection with the initial underwritten public offering of the Company's securities pursuant to a registration statement under the Securities Act of 1933, as amended (the "**Securities Act**"): (i) not to sell, make short sale of, loan, grant any options for the purchase of, or otherwise dispose of any shares of Common Stock held by the Participant (other than those shares included in the offering) without the prior written consent of the Company or the underwriters managing such initial underwritten public offering of the Company's securities for a period of 180 days from the effective date of such registration statement, which period may be extended upon the request of the underwriters for an additional period of up to fifteen (15) days if the Company issues or proposes to issue an earnings or other public release within fifteen (15) days of the expiration of the 180-day lockup period, and (ii) to execute any agreement reflecting clause (i) above as may be requested by the Company or the managing underwriters at the time of such offering.

The Participant agrees to execute and deliver such other agreements as may be reasonably requested by the Company or the underwriters of such offering which are consistent with the foregoing or which are necessary to give further effect thereto. In addition, if requested by the Company or the underwriters of such offering, the Participant shall provide, within 10 days of such request, such information as may be required by the Company or such underwriters in connection with the completion of any public offering of the Company's securities pursuant to a registration statement filed under the Securities Act. The obligations described in this Section 5 shall not apply to a registration relating solely to employee benefits plans on Form S-1 or Form S-8 or similar forms that may be promulgated in the future, or a registration relating solely to a Commission Rule 145 transaction on Form S-4 or similar forms that may be promulgated in the future. The Company may impose stop-transfer instructions with respect to the shares of Common Stock (or other securities) subject to the foregoing restriction until the end of the applicable period. Participant agrees that any transferee of this Option or Shares pursuant to this Agreement shall be bound by this Section 5.

6. Tax Matters.

(a) Withholding. No Shares shall be issued pursuant to the exercise of this Option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this Option.

(b) Disqualifying Disposition. If the Participant disposes of Shares acquired upon exercise of this Option within two years from the Grant Date or one year after such Shares were acquired pursuant to exercise of this Option, the Participant shall immediately notify the Company in writing of such disposition and shall timely satisfy all resulting tax obligations and shall hold the Company harmless with respect to any such tax obligations.

(c) Code Section 409A. The Exercise Price is intended to be the Fair Market Value of the Common Stock on the Grant Date. The Company has determined the Fair Market Value of the Common Stock in good faith and using the reasonable application of a reasonable valuation method, for purposes of determining the Exercise Price. Notwithstanding this, the Internal Revenue Service may assert that the Fair Market Value of the Common Stock on the Grant Date was greater than the Exercise Price. Under Code Section 409A, if the Exercise Price is less than the Fair Market Value of the Common Stock as of the Grant Date, this Option may be treated as a form of deferred compensation and the Participant may be subject to an additional twenty percent (20%) tax, plus interest and possible penalties. The Participant acknowledges that the Company has advised the Participant to consult with a tax adviser regarding the potential impact of Code Section 409A and that the Company, in the exercise of its sole discretion and without the consent of the Participant, may amend or modify this Agreement in any manner and delay the payment of any amounts payable pursuant to this Agreement to the minimum extent necessary to meet the requirements of Code Section 409A, as amplified by any Internal Revenue Service or U.S. Treasury Department regulations or guidance as the Company deems appropriate or advisable.

7. Nontransferability of Option. This Option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this Option shall be exercisable only by the Participant.

8. Provisions of the Plan. This Option is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this Option.

9 Entire Agreement; Governing Law. The Plan and the accompanying Notice are incorporated herein by reference. This Agreement, the Notice and the Plan constitute the entire agreement between the Company and the Participant with respect to the subject matter hereof and supersede in their entirety all prior undertakings and agreements of the Company and the Participant with respect to the subject matter hereof. This Agreement shall be governed by and construed in accordance with the General Corporation Law of the State of Delaware, as to matters within the scope thereof, and the internal laws of the State of North Carolina (without reference to conflict of law provisions), as to all other matters.

10. Amendment. Except as set forth in Section 6(c), this Agreement may not be modified or amended in any manner adverse to the Participant's interest except by means of a writing signed by the Company and Participant.

11. No Guarantee of Continued Service. THE PARTICIPANT ACKNOWLEDGES AND AGREES THAT THE VESTING OF OPTIONS PURSUANT TO THE VESTING SCHEDULE SET FORTH HEREIN AND IN THE NOTICE ARE EARNED ONLY BY CONTINUING SERVICE AT THE WILL OF THE COMPANY (NOT THROUGH THE ACT OF BEING HIRED, BEING GRANTED THIS OPTION OR ACQUIRING SHARES HEREUNDER). THE PARTICIPANT FURTHER ACKNOWLEDGES AND AGREES THAT THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREUNDER AND THE VESTING SCHEDULE SET FORTH HEREIN DO NOT CONSTITUTE AN EXPRESS OR IMPLIED PROMISE OF CONTINUED SERVICE FOR THE VESTING PERIOD, FOR ANY PERIOD, OR AT ALL, AND SHALL NOT INTERFERE IN ANY WAY WITH PARTICIPANT'S RIGHT OR THE COMPANY'S RIGHT TO TERMINATE PARTICIPANT'S SERVICE WITH OR WITHOUT CAUSE.

* * *

Exhibit A

INNOVATE BIOPHARMACEUTICALS INC.

NOTICE OF INCENTIVE STOCK OPTION EXERCISE
2015 STOCK INCENTIVE PLAN

The undersigned (the "**Participant**") has previously been awarded an incentive stock option (the "**Option**") to purchase shares (the "**Shares**") of the common stock of Innovate Biopharmaceuticals Inc., a Delaware corporation (the "**Company**"), pursuant to the Company's 2015 Stock Incentive Plan (the "**Plan**"), and hereby notifies the Company of the Participant's desire to exercise the Option on the terms set forth herein:

PARTICIPANT INFORMATION:		**OPTION INFORMATION:**	
Name:	_____	Grant Date:	_____
Address:	_____	Exercise Price Per Share:	$_____
	_____		
Taxpayer ID #:	_____	Total Shares Covered by Option:	_____

EXERCISE INFORMATION:

Number of Shares Being Purchased:	_____
Aggregate Exercise Price:	$_____
Form of Payment (check all that apply):	☐ Check for $_____ made payable to "Innovate Biopharmaceuticals Inc."
	☐ Cash in the amount of $_____
Please register the Shares in my name as follows:	_____ (Print name as it is to appear on stock certificate)

REPRESENTATIONS AND WARRANTIES OF THE PARTICIPANT:

The Participant hereby represents and warrants to the Company that, as of the date hereof:

1. I am purchasing the Shares for my own account for investment only, and not with a view to, or for sale in connection with, any distribution of the Shares in violation of the Securities Act of 1933 (the "**Securities Act**"), or any rule or regulation under the Securities Act.

2. I have had such opportunity as I have deemed adequate to obtain from representatives of the Company such information as is necessary to permit me to evaluate the merits and risks of my investment in the Company.

3. I have sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in the purchase of the Shares and to make an informed investment decision with respect to such purchase.

4. I can afford a complete loss of the value of the Shares and am able to bear the economic risk of holding such Shares for an indefinite period.

5. I acknowledge that I am acquiring the Shares subject to all other terms of the Plan, including the Notice of Incentive Stock Option and related Incentive Stock Option Agreement.

6. I acknowledge that the Company has encouraged me to consult my own adviser to determine the tax consequences of acquiring the Shares at this time. I acknowledge that the Company has encouraged me to consult my own adviser to determine the form of ownership that is appropriate for me.

7. I acknowledge that the Shares remain subject to the Company's right of first refusal and the market stand-off (sometimes referred to as the "lock-up"), all in accordance with the applicable Notice of Incentive Stock Option and related Incentive Stock Option Agreement.

8. I understand that (i) the Shares have not been registered under the Securities Act and are "restricted securities" within the meaning of Rule 144 under the Securities Act, (ii) the Shares cannot be sold, transferred or otherwise disposed of unless they are subsequently registered under the Securities Act or an exemption from registration is then available; (iii) in any event, the exemption from registration under Rule 144 will not be available for at least six months or one year (depending on whether the Company is subject to the reporting obligations of the Securities Exchange Act of 1934, as amended) and even then will not be available unless applicable terms and conditions of Rule 144 are complied with; and (iv) there is now no registration statement on file with the Securities and Exchange Commission with respect to any stock of the Company and the Company has no obligation or current intention to register the Shares under the Securities Act.

_____

(Print Participant Name)

_____

(Signature)

Date: _____

Exhibit 10.13

INNOVATE BIOPHARMACEUTICALS INC.

NOTICE OF NONSTATUTORY STOCK OPTION
2015 STOCK INCENTIVE PLAN

Innovate Biopharmaceuticals Inc., a Delaware corporation (the "**Company**") grants to the undersigned (the "**Participant**") the following nonstatutory stock option to purchase shares (the "**Shares**") of the common stock of the Company (the "**Common Stock**") pursuant to the Company's 2015 Stock Incentive Plan (the "**Plan**"):

Participant:	***[**Participant Name**]**
Total Number of Shares:	***[**Number of Shares**]**
Grant Date:	***[**Grant Date**]**
Exercise Price per Share:	$***[**Exercise Price**]**
Vesting Commencement Date:	***[**Vesting Date**]**
Vesting Schedule:	***[**Vesting Schedule**]** ***[**In addition, this option may vest and become exercisable on an accelerated basis under Section 2 of the Nonstatutory Stock Option Agreement.**]**
Final Exercise Date:	***[**Expiration Date**]** This option may expire earlier pursuant to Section 3 of the Nonstatutory Stock Option Agreement if the Participant's relationship with the Company is terminated, or pursuant to Section 8 of the Plan.

This nonstatutory stock option is granted under and governed by the terms and conditions of the Plan and the accompanying Nonstatutory Stock Option Agreement, both of which are incorporated herein by reference. By signing below, the Participant accepts this nonstatutory stock option, acknowledges receipt of a copy of the Plan and the Nonstatutory Stock Option Agreement, and agrees to the terms thereof.

[PARTICIPANT NAME]:

_____
(Signature)

Address: _____

_____

INNOVATE BIOPHARMACEUTICALS INC.:

By: _____

Name: _____

Title: _____

Date: _____

THE OPTION GRANTED PURSUANT TO THIS AGREEMENT AND THE SHARES ISSUABLE UPON THE EXERCISE THEREOF HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY STATE SECURITIES LAWS, AND MAY NOT BE SOLD, PLEDGED OR OTHERWISE TRANSFERRED WITHOUT AN EFFECTIVE REGISTRATION THEREOF UNDER SUCH ACT OR APPLICABLE LAWS OR AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY AND ITS COUNSEL THAT SUCH REGISTRATION IS NOT REQUIRED.

INNOVATE BIOPHARMACEUTICALS INC.

NONSTATUTORY STOCK OPTION AGREEMENT
Granted Under 2015 Stock Incentive Plan

1. Grant of Option.

This Nonstatutory Stock Option Agreement (the "**Agreement**") evidences the grant by Innovate Biopharmaceuticals Inc., a Delaware corporation (the "**Company**"), on the Grant Date to the Participant, a**[**n**]** ***[**employee/officer/director/consultant/advisor**]** of the Company, of an option (this "**Option**") to purchase, in whole or in part, on the terms provided herein and in the Plan, the Total Number of Shares of Common Stock at the Exercise Price per Share, all as defined and set forth in the accompanying Notice of Nonstatutory Stock Option (the "**Notice**"). Capitalized terms that are not otherwise defined herein or in the Notice shall have the meanings given to such terms in the Plan.

It is intended that this Option shall not be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "**Code**"). Except as otherwise indicated by the context, the term "Participant," as used in this Agreement, shall include any person who acquires the right to exercise this Option validly under its terms.

2. Vesting Schedule.

This Option shall vest and become exercisable at the time or times set forth in the accompanying Notice. **[**In addition, the Option may vest and become exercisable on an accelerated basis as follows:]

***[**Insert any applicable acceleration provisions.**]**

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this Option shall be in writing in substantially the form of the Notice of Stock Option Exercise attached to this Agreement as **Exhibit A**, signed by the Participant, and received by the Company at its principal office, accompanied by this Agreement, and payment in full in the manner provided in the Plan. The Participant may purchase less than the number of Shares subject to this Option; provided that, no partial exercise of this Option may be for any fractional share.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this Option may not be exercised unless the Participant, at the time of the exercise of this Option, is, and has been at all times since the Grant Date, a Service Provider to or of the Company or any subsidiary of the Company as defined in Section 424 (f) of the Code (an "**Eligible Participant**").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this Option shall terminate three months after such cessation (but in no event after the Final Exercise Date); provided that, this Option shall be exercisable only to the extent that the Participant was entitled to exercise this Option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the non-competition or confidentiality provisions of any employment agreement, confidentiality and nondisclosure agreement, or other agreement between the Participant and the Company, the right to exercise this Option shall terminate immediately upon such violation.

(d) Exercise Period Upon Death or Disability. If the Participant dies or becomes disabled (within the meaning of Section 22(e)(3) of the Code) prior to the Final Exercise Date while the Participant is an Eligible Participant and the Company has not terminated such relationship for "Cause" (as defined below), this Option shall be exercisable, within the period of one year following the date of death or disability of the Participant, by the Participant (or in the case of death by an authorized transferee); provided that, this Option shall be exercisable only to the extent that this Option was exercisable by the Participant on the date of the Participant's death or disability, and further provided that this Option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's status as a Service Provider is terminated by the Company for Cause (as defined below), the right to exercise this Option shall terminate immediately upon the effective date of such termination. If the Participant is party to an agreement with the Company that contains an applicable definition of "cause", "**Cause**" shall have the meaning ascribed to such term in such agreement. Otherwise, "**Cause**" shall mean willful misconduct by the Participant or willful failure by the Participant to perform the Participant's responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been discharged for "Cause" if the Company determines, within 30 days after the Participant's resignation, that discharge for cause was warranted.

4. Restrictions on Transfer; Rights of First Refusal and Stockholder Agreements.

(a) Bylaws. The Participant acknowledges and agrees that the Shares are subject to the provisions of the Company's Bylaws, as amended from time to time (the "**Bylaws**"), including without limitation, all restrictions on transfer and rights of first refusal described in the Bylaws. The Participant may inspect the Bylaws at the Company's principal office.

(b) Legend. Any certificate representing Shares shall bear a legend substantially in the following form (in addition to, or in combination with, any legend required by applicable federal and state securities laws and agreements relating to the transfer and/or voting of the Company's securities):

> "The securities represented by this certificate, and the transfer thereof, are subject to the restriction on transfer provisions of the Bylaws of the Company, a copy of which is on file in, and may be examined at, the principal office of the Company."

(c) Stockholder Agreements. The Participant acknowledges and agrees that **[**the Company may condition the issuance of the Shares upon the Participant joining and becoming a party to such stockholder agreements, which may impose certain contractual rights and obligations on the Shares, as may be entered into from time to time by and among the Company and certain holders of the Company's capital stock**.**

5. Agreement in Connection with Public Offering.

The Participant agrees, in connection with the initial underwritten public offering of the Company's securities pursuant to a registration statement under the Securities Act of 1933, as amended (the "**Securities Act**"): (i) not to sell, make short sale of, loan, grant any options for the purchase of, or otherwise dispose of any shares of Common Stock held by the Participant (other than those shares included in the offering) without the prior written consent of the Company or the underwriters managing such initial underwritten public offering of the Company's securities for a period of 180 days from the effective date of such registration statement, which period may be extended upon the request of the underwriters for an additional period of up to fifteen (15) days if the Company issues or proposes to issue an earnings or other public release within fifteen (15) days of the expiration of the 180-day lockup period, and (ii) to execute any agreement reflecting clause (i) above as may be requested by the Company or the managing underwriters at the time of such offering.

The Participant agrees to execute and deliver such other agreements as may be reasonably requested by the Company or the underwriters of such offering which are consistent with the foregoing or which are necessary to give further effect thereto. In addition, if requested by the Company or the underwriters of such offering, the Participant shall provide, within 10 days of such request, such information as may be required by the Company or such underwriters in connection with the completion of any public offering of the Company's securities pursuant to a registration statement filed under the Securities Act. The obligations described in this Section 5 shall not apply to a registration relating solely to employee benefits plans on Form S-1 or Form S-8 or similar forms that may be promulgated in the future, or a registration relating solely to a Commission Rule 145 transaction on Form S-4 or similar forms that may be promulgated in the future. The Company may impose stop-transfer instructions with respect to the shares of Common Stock (or other securities) subject to the foregoing restriction until the end of the applicable period. Participant agrees that any transferee of this Option or Shares pursuant to this Agreement shall be bound by this Section 5.

6. Tax Matters.

(a) Withholding. No Shares shall be issued pursuant to the exercise of this Option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding or other taxes required by law to be withheld in respect of this Option.

(b) Code Section 409A. The Exercise Price is intended to be not less than the Fair Market Value of the Common Stock on the Grant Date. The Company has determined the Fair Market Value of the Common Stock in good faith and using the reasonable application of a reasonable valuation method, for purposes of determining the Exercise Price. Notwithstanding this, the Internal Revenue Service may assert that the Fair Market Value of the Common Stock on the Grant Date was greater than the Exercise Price. Under Code Section 409A, if the Exercise Price is less than the Fair Market Value of the Common Stock as of the Grant Date, this Option may be treated as a form of deferred compensation and the Participant may be subject to an additional twenty percent (20%) tax, plus interest and possible penalties. The Participant acknowledges that the Company has advised the Participant to consult with a tax adviser regarding the potential impact of Code Section 409A and that the Company, in the exercise of its sole discretion and without the consent of the Participant, may amend or modify this Agreement in any manner and delay the payment of any amounts payable pursuant to this Agreement to the minimum extent necessary to meet the requirements of Code Section 409A, as amplified by any Internal Revenue Service or U.S. Treasury Department regulations or guidance as the Company deems appropriate or advisable.

7. Nontransferability of Option. This Option may not be sold, assigned, transferred, pledged or otherwise encumbered by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this Option shall be exercisable only by the Participant.

8. Provisions of the Plan. This Option is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this Option.

9 Entire Agreement; Governing Law. The Plan and the Notice are incorporated herein by reference. This Agreement, the Notice and the Plan constitute the entire agreement between the Company and the Participant with respect to the subject matter hereof and supersede in their entirety all prior undertakings and agreements of the Company and the Participant with respect to the subject matter hereof. This Agreement shall be governed by and construed in accordance with the General Corporation Law of the State of Delaware, as to matters within the scope thereof, and the internal laws of the State of North Carolina (without reference to conflict of law provisions), as to all other matters.

10. Amendment. Except as set forth in Section 6(b), this Agreement may not be modified or amended in any manner adverse to the Participant's interest except by means of a writing signed by the Company and Participant.

11. No Guarantee of Continued Service. THE PARTICIPANT ACKNOWLEDGES AND AGREES THAT THE VESTING OF OPTIONS PURSUANT TO THE VESTING SCHEDULE SET FORTH HEREIN AND IN THE NOTICE ARE EARNED ONLY BY CONTINUING SERVICE AT THE WILL OF THE COMPANY (NOT THROUGH THE ACT OF BEING HIRED, BEING GRANTED THIS OPTION OR ACQUIRING SHARES HEREUNDER). THE PARTICIPANT FURTHER ACKNOWLEDGES AND AGREES THAT THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREUNDER AND THE VESTING SCHEDULE SET FORTH HEREIN DO NOT CONSTITUTE AN EXPRESS OR IMPLIED PROMISE OF CONTINUED SERVICE FOR THE VESTING PERIOD, FOR ANY PERIOD, OR AT ALL, AND SHALL NOT INTERFERE IN ANY WAY WITH PARTICIPANT'S RIGHT OR THE COMPANY'S RIGHT TO TERMINATE PARTICIPANT'S SERVICE WITH OR WITHOUT CAUSE.

* * * * * * * * * * *

Exhibit A

INNOVATE BIOPHARMACEUTICALS INC.

NOTICE OF NONSTATUTORY STOCK OPTION EXERCISE
2015 STOCK INCENTIVE PLAN

The undersigned (the "**Participant**") has previously been awarded a nonstatutory stock option (the "**Option**") to purchase shares (the "**Shares**") of the common stock of Innovate Biopharmaceuticals Inc., a Delaware corporation (the "**Company**"), pursuant to the Company's 2015 Stock Incentive Plan (the "**Plan**"), and hereby notifies the Company of the Participant's desire to exercise the Option on the terms set forth herein:

PARTICIPANT INFORMATION:		**OPTION INFORMATION:**	
Name:	_____	Grant Date:	_____
Address:	_____	Exercise Price Per Share:	$_____
	_____		
Taxpayer ID #:	_____	Total Shares Covered by Option:	_____

EXERCISE INFORMATION:	
Number of Shares Being Purchased:	_____
Aggregate Exercise Price:	$_____
Form of Payment (check all that apply):	☐ Check for $_____ made payable to "Innovate Biopharmaceuticals Inc."
	☐ Cash in the amount of $_____
Please register the Shares in my name as follows:	_____ (Print name as it is to appear on stock certificate)

REPRESENTATIONS AND WARRANTIES OF THE PARTICIPANT:

The Participant hereby represents and warrants to the Company that, as of the date hereof:

1. I am purchasing the Shares for my own account for investment only, and not with a view to, or for sale in connection with, any distribution of the Shares in violation of the Securities Act of 1933 (the "**Securities Act**"), or any rule or regulation under the Securities Act.

2. I have had such opportunity as I have deemed adequate to obtain from representatives of the Company such information as is necessary to permit me to evaluate the merits and risks of my investment in the Company.

3. I have sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in the purchase of the Shares and to make an informed investment decision with respect to such purchase.

4. I can afford a complete loss of the value of the Shares and am able to bear the economic risk of holding such Shares for an indefinite period.

5. I acknowledge that I am acquiring the Shares subject to all other terms of the Plan, including the Notice of Nonstatutory Stock Option and related Nonstatutory Stock Option Agreement.

6. I acknowledge that the Company has encouraged me to consult my own adviser to determine the tax consequences of acquiring the Shares at this time. I acknowledge that the Company has encouraged me to consult my own adviser to determine the form of ownership that is appropriate for me.

7. I acknowledge that the Shares remain subject to the Company's right of first refusal and the market stand-off (sometimes referred to as the "lock-up"), all in accordance with the applicable Notice of Nonstatutory Stock Option and related Nonstatutory Stock Option Agreement.

8. I understand that (i) the Shares have not been registered under the Securities Act and are "restricted securities" within the meaning of Rule 144 under the Securities Act, (ii) the Shares cannot be sold, transferred or otherwise disposed of unless they are subsequently registered under the Securities Act or an exemption from registration is then available; (iii) in any event, the exemption from registration under Rule 144 will not be available for at least six months or one year (depending on whether the Company is subject to the reporting obligations of the Securities Exchange Act of 1934, as amended) and even then will not be available unless applicable terms and conditions of Rule 144 are complied with; and (iv) there is now no registration statement on file with the Securities and Exchange Commission with respect to any stock of the Company and the Company has no obligation or current intention to register the Shares under the Securities Act.

_____

(Print Participant Name)

_____

(Signature)

Date: _____

Exhibit 10.14

INNOVATE BIOPHARMACEUTICALS INC.
SUMMARY OF RESTRICTED STOCK PURCHASE
2015 STOCK INCENTIVE PLAN

Innovate Biopharmaceuticals Inc., a Delaware corporation (the "**Company**"), hereby issues and sells to the undersigned (the "**Participant**"), and the Participant hereby purchases from the Company, shares (the "**Shares**") of the common stock of the Company (the "**Common Stock**"), pursuant to the Company's 2015 Stock Incentive Plan (the "**Plan**"):

Participant:	*[Participant Name]
Total Number of Shares:	*[Number of Shares]
Purchase Date:	*[Purchase Date]
Purchase Price per Share:	$*[Purchase Price]
Vesting Commencement Date:	*[Vesting Date]
Vesting Schedule:	*[Describe Vesting Schedule]
	*[In addition, the Right of Repurchase shall lapse on an accelerated basis under Section 2 of the Restricted Stock Purchase Agreement.]

This restricted stock purchase is governed by the terms and conditions of the Plan and the Restricted Stock Purchase Agreement, both of which are incorporated herein by reference. By signing below, the Participant acknowledges receipt of a copy of the Plan and the Restricted Stock Purchase Agreement, and purchases the Shares on the terms set forth herein and therein.

***[PARTICIPANT NAME]:**

_____
(Signature)

Address: _____

_____

INNOVATE BIOPHARMACEUTICALS INC.:

By: _____

Name: _____

Title: _____

Date: _____

SHARES PURCHASED HEREUNDER HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR ANY STATE SECURITIES LAWS, AND MAY NOT BE SOLD, PLEDGED OR OTHERWISE TRANSFERRED WITHOUT AN EFFECTIVE REGISTRATION THEREOF UNDER SUCH ACT OR APPLICABLE LAWS OR AN OPINION OF COUNSEL SATISFACTORY TO THE COMPANY AND ITS COUNSEL THAT SUCH REGISTRATION IS NOT REQUIRED.

INNOVATE BIOPHARMACEUTICALS INC.

RESTRICTED STOCK PURCHASE AGREEMENT
2015 STOCK INCENTIVE PLAN

1. Purchase of Shares. The Company hereby issues and sells to the Participant, and the Participant hereby purchases from the Company, subject to the terms and conditions set forth in this Agreement and in the Plan, the Total Number of Shares at a price per share equal to the Purchase Price per Share, all as defined and set forth in the accompanying Summary of Restricted Stock Purchase. The aggregate purchase price for the Shares shall be paid by the Participant by a check payable to the order of the Company or such other method as may be acceptable to the Company. Upon receipt of said consideration by the Company for the Shares, the Company shall issue to the Participant one or more certificates in the name of the Participant for that number of the Shares purchased by the Participant.

2. Right of Repurchase. The Participant shall vest in, and the Company shall have a right of repurchase with respect to, the Shares (the "**Right of Repurchase**"), which such Right of Repurchase shall lapse according to the Vesting Schedule set forth in the accompanying Summary of Restricted Stock Purchase. **[**In addition, the Right of Repurchase shall lapse on an accelerated basis as follows:

***[**Insert any applicable acceleration provisions**]**

3. Exercise of Right of Repurchase and Closing.

(a) In the event the Participant ceases to be a Service Provider for any reason (other than Cause, as defined below) or no reason, including, without limitation, by reason of Participant's death or disability (as defined in Section 22(e)(3) of the Internal Revenue Code of 1986, as amended (the "**Code**"), the Company shall, upon the date of such termination (as reasonably fixed by the Company), have an irrevocable, exclusive right to purchase some or all of the Shares which have not yet vested and been released from the Right of Repurchase, at a price per share equal to the lesser of (x) the fair market value of the shares at the time the Right of Repurchase is exercised, as determined by the Company's board of directors and (y) the Purchase Price (the "**Repurchase Price**"). If, prior to the date on which the Shares are fully vested pursuant to the Vesting Schedule or any applicable vesting acceleration provision, (i) the Participant violates the non-competition, confidentiality or other provisions of any employment agreement, confidentiality, inventions and/or nondisclosure agreement, or other agreement between the Participant and the Company or (ii) the Participant's status as a Service Provider is terminated by the Company for Cause (as defined below), the Company's Right of Repurchase shall apply to the Total Number of Shares, and the Company shall have an irrevocable, exclusive right to purchase some or all of the Total Number of Shares, at the Repurchase Price. The number of Shares as to which the Right of Repurchase applies, as set forth in the preceding two sentences, shall be referred to herein as the "**Repurchase Shares**."

(b) The Company may exercise the Right of Repurchase as to any or all of the Repurchase Shares at any time following the Participant's termination; provided, however, that without requirement of further action on the part of either party hereto, the Company's Right of Repurchase shall be deemed to have been automatically exercised as to all Repurchase Shares at 5:00 p.m. EDT on the date that is 90 days following the date of the Participant's termination, unless the Company declines in writing to exercise the Right of Repurchase prior to such time.

(c) If the Company decides not to exercise the Right of Repurchase, it shall notify the Participant within 90 days of the Participant's termination. If the Company decides to exercise its Right of Repurchase, the Company shall deliver payment (if any) to the Participant, with a copy to the Escrow Agent (as defined in Section 6 hereof), by any of the following methods, in the Company's sole discretion: (i) delivering to the Participant or the Participant's executor a check in the amount of the aggregate Repurchase Price; (ii) canceling an amount of the Participant's indebtedness to the Company equal to the aggregate Repurchase Price; or (iii) any combination of (i) and (ii) such that the combined payment and cancellation of indebtedness equals such aggregate Repurchase Price. Upon delivery of the payment of the aggregate Repurchase Price in any of the ways described above, the Company shall become the legal and beneficial owner of the Repurchase Shares being repurchased and all related rights and interests therein, and the Company shall have the right to retain and transfer to its own name the number of Repurchase Shares being repurchased by the Company. In the event that Participant's continuous status as a Service Provider terminates, and the Company neither notifies the Participant within 90 days thereafter of the Company's decision not to exercise the Right of Repurchase, nor delivers payment of the Repurchase Price to the Participant within 90 days thereafter, then the sole remedy of the Participant thereafter shall be to receive the applicable Repurchase Price determined as set forth above from the Company in the manner set forth above, and in no case shall the Participant have any claim of ownership as to any of the Repurchase Shares.

(d) The Company in its sole discretion may designate and assign one or more employees, officers, directors or stockholders of the Company or other persons or organizations to exercise all or a part of the Company's Right of Repurchase to purchase all or a part of the Repurchase Shares.

(e) The Company or its assignee must notify the Participant that it does not elect to exercise the Right of Repurchase conferred above by giving the requisite written notice within 90 days following Participant's termination as a Service Provider to the Company. If the Company or its assignee gives such requisite notice, the Repurchase Option shall terminate.

(f) In the event that the Right of Repurchase is exercised, whether automatically in the manner provided for above or pursuant to written notice, then upon and following such exercise, the only remaining right of the Participant under this Agreement shall be the right to receive the applicable Repurchase Price, and the Participant have no right whatsoever to receive the Repurchase Shares. In the event that the Company's Right of Repurchase is terminated pursuant to clause (e) above, then upon and following such termination, the only remaining right of the Participant under this Agreement shall be the right to receive the Repurchase Shares, and the Participant shall have no right whatsoever to receive the Repurchase Price

(g) For purposes hereof, if the Participant is party to an agreement with the Company that contains an applicable definition of "cause", "Cause" shall have the meaning ascribed to such term in such agreement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform the Participant's responsibilities to the Company (including, without limitation, breach by the Participant of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been discharged for Cause if the Company determines, within 30 days after the Participant's resignation, that discharge for cause was warranted.

4. Restrictions on Transfer; Rights of First Refusal and Stockholder Agreements.

(a) The Participant acknowledges and agrees that the Shares are subject to the provisions of the Company's Bylaws, as amended from time to time (the "**Bylaws**"), including without limitation, all restrictions on transfer and rights of first refusal described in the Bylaws. The Participant may inspect the Bylaws at the Company's principal office.

(b) Legends. Any certificate representing Shares shall bear legends substantially in the following form (in addition to, or in combination with, any legend required by applicable federal and state securities laws and agreements relating to the transfer and/or voting of the Company's securities):

> "The securities represented by this certificate are subject to restrictions on transfer and an option to purchase set forth in a restricted stock agreement between the Company and the registered owner of these shares (or such owner's predecessor in interest), and such restricted stock agreement is available for inspection without charge at the principal office of the Company."
>
> "The securities represented by this certificate, and the transfer thereof, are subject to the restriction on transfer provisions of the Bylaws of the Company, a copy of which is on file in, and may be examined at, the principal office of the Company."

(c) Stockholder Agreements. The Participant acknowledges and agrees that upon the request of the Company, the Participant shall join and become a party to such stockholder agreements, which may impose certain contractual rights and obligations on the Shares, as may be entered into from time to time by and among the Company and the holders of the Company's capital stock**.**

5. Agreement in Connection with Public Offering. The Participant agrees, in connection with the initial underwritten public offering of the Company's securities pursuant to a registration statement under the Securities Act of 1933, as amended (the "**Securities Act**"): (i) not to sell, make short sale of, loan, grant any options for the purchase of, or otherwise dispose of any shares of Common Stock held by the Participant (other than those shares included in the offering) without the prior written consent of the Company or the underwriters managing such initial underwritten public offering of the Company's securities for a period of 180 days from the effective date of such registration statement, which period may be extended upon the request of the underwriters for an additional period of up to fifteen (15) days if the Company issues or proposes to issue an earnings or other public release within fifteen (15) days of the expiration of the 180-day lockup period, and (ii) to execute any agreement reflecting clause (i) above as may be requested by the Company or the managing underwriters at the time of such offering.

The Participant agrees to execute and deliver such other agreements as may be reasonably requested by the Company or the underwriters of such offering which are consistent with the foregoing or which are necessary to give further effect thereto. In addition, if requested by the Company or the underwriters of such offering, the Participant shall provide, within 10 days of such request, such information as may be required by the Company or such underwriters in connection with the completion of any public offering of the Company's securities pursuant to a registration statement filed under the Securities Act. The obligations described in this Section 5 shall not apply to a registration relating solely to employee benefits plans on Form S-1 or Form S-8 or similar forms that may be promulgated in the future, or a registration relating solely to a Commission Rule 145 transaction on Form S-4 or similar forms that may be promulgated in the future. The Company may impose stop-transfer instructions with respect to the shares of Common Stock (or other securities) subject to the foregoing restriction until the end of the applicable period. Participant agrees that any transferee of the Shares pursuant to this Agreement shall be bound by this Section 5.

6. Escrow. The Participant shall, upon the execution of this Agreement, execute Joint Escrow Instructions in the form attached to this Agreement as **Exhibit A**. The Joint Escrow Instructions shall be delivered to the Secretary of the Company, as escrow agent thereunder (the "**Escrow Agent**"). The Participant shall deliver to the Escrow Agent a stock assignment duly endorsed in blank, in the form attached to this Agreement as **Exhibit B**, and hereby instructs the Company to deliver to the Escrow Agent, on behalf of the Participant, the certificate(s) evidencing the Shares issued hereunder. Such materials shall be held by the Escrow Agent pursuant to the terms of the Joint Escrow Instructions.

7. Provisions of the Plan.

(a) This Agreement is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this Agreement.

(b) As provided in the Plan, upon the occurrence of a Change in Control, the repurchase and other rights of the Company hereunder shall inure to the benefit of the Company's successor and shall apply to the cash, securities or other property which the Shares were converted into or exchanged for pursuant to such Change in Control in the same manner and to the same extent as they applied to the Shares under this Agreement. If, in connection with a Change in Control, a portion of the cash, securities and/or other property received upon the conversion or exchange of the Shares is to be deferred, contingent or placed into escrow to secure indemnification or for other reasons, the mix between the vested and unvested portion of such cash, securities and/or other property that is deferred, contingent or placed into escrow shall be the same as the mix between the vested and unvested portion of such cash, securities and/or other property that is not subject to deferral, contingence or escrow.

8. Investment Representations. The Participant represents, warrants and covenants as follows:

(a) The Participant is purchasing the Shares for the Participant's own account for investment only, and not with a view to, or for sale in connection with, any distribution of the Shares in violation of the Securities Act, or any rule or regulation under the Securities Act.

(b) The Participant has had such opportunity as the Participant deems adequate to obtain from representatives of the Company such information as is necessary to permit the Participant to evaluate the merits and risks of the Participant's investment in the Company.

(c) The Participant has sufficient experience in business, financial and investment matters to be able to evaluate the risks involved in the purchase of the Shares and to make an informed investment decision with respect to such purchase.

(d) The Participant can afford a complete loss of the value of the Shares and is able to bear the economic risk of holding such Shares for an indefinite period.

(e) The Participant acknowledges that the Participant is acquiring the Shares subject to all other terms of the Plan and this Agreement, including the related Summary of Restricted Stock Purchase

(f) The Participant acknowledges that the Company has encouraged the Participant to consult the Participant's own adviser to determine the tax consequences of acquiring the Shares at this time.

(g) The Participant acknowledges that the Shares shall be subject to the Company's Right of Repurchase, right of first refusal and the market stand-off (sometimes referred to as the "lock-up"), all in accordance with the related Summary of Restricted Stock Purchase and this Agreement.

(h) The Participant understands that (i) the Shares have not been registered under the Securities Act and are "restricted securities" within the meaning of Rule 144 under the Securities Act, (ii) the Shares cannot be sold, transferred or otherwise disposed of unless they are subsequently registered under the Securities Act or an exemption from registration is then available; (iii) in any event, the exemption from registration under Rule 144 will not be available for at least six months or one year (depending on whether the Company is subject to the reporting obligations of the Securities Exchange Act of 1934, as amended) and even then will not be available unless applicable terms and conditions of Rule 144 are complied with; and (iv) there is now no registration statement on file with the Securities and Exchange Commission with respect to any stock of the Company and the Company has no obligation or current intention to register the Shares under the Securities Act.

9. Withholding Taxes; Section 83(b) Election.

(a) The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state or local taxes of any kind required by law to be withheld with respect to the purchase of the Shares by the Participant or the lapse of the Repurchase Option.

(b) The Participant has reviewed with the Participant's own tax advisors the federal, state, local and foreign tax consequences of this investment and the transactions contemplated by this Agreement. The Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents. The Participant understands that the Participant (and not the Company) shall be responsible for the Participant's own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement. The Participant understands that as a condition to the issuance of the Shares, Participant shall be required to file an election under Section 83(b) of the Internal Revenue Code of 1986 with the I.R.S. within 30 days from the date of this Agreement; if such election is not filed on a timely basis, the Company shall declare this Agreement, and the offer to issue the Shares, void. In such event, the Company shall return the full amount of the Purchase Price previously paid to the Participant. The Company shall not issue a stock certificate with respect to the Shares unless and until the 83(b) election has been timely filed.

THE PARTICIPANT ACKNOWLEDGES THAT IT IS SOLELY THE PARTICIPANT'S RESPONSIBILITY, AND NOT THE COMPANY'S, TO FILE TIMELY THE ELECTION UNDER SECTION 83(b), EVEN IF THE PARTICIPANT REQUESTS THE COMPANY OR ITS REPRESENTATIVES TO MAKE THIS FILING ON THE PARTICIPANT'S BEHALF.

10. Miscellaneous.

(a) No Rights to Continued Service. The Participant acknowledges and agrees that the vesting of the Shares is earned only by continuing service as a Service Provider at the will of the Company (not through the act of being hired or purchasing shares hereunder). The Participant further acknowledges and agrees that the transactions contemplated hereunder and the vesting schedule set forth herein do not constitute an express or implied promise of continued engagement as an employee or consultant for the vesting period, for any period, or at all.

(b) Severability. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, and each other provision of this Agreement shall be severable and enforceable to the extent permitted by law.

(c) Waiver. Any provision for the benefit of the Company contained in this Agreement may be waived, either generally or in any particular instance, by the Board of Directors of the Company.

(d) Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Company and the Participant and their respective heirs, executors, administrators, legal representatives, successors and assigns, subject to the restrictions on transfer set forth in Section 4 of this Agreement.

(e) Notice. All notices required or permitted hereunder shall be in writing and deemed effectively given upon personal delivery or five days after deposit in the United States Post Office, by registered or certified mail, postage prepaid, addressed to the other party hereto at the address shown beneath his or its respective signature to this Agreement, or at such other address or addresses as either party shall designate to the other in accordance with this Section 10(e).

(f) Pronouns. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular form of nouns and pronouns shall include the plural, and vice versa.

(g) Entire Agreement; Governing Law. The Plan and the Bylaws are incorporated herein by reference. This Agreement, the Plan, and the Bylaws constitute the entire agreement between the Company and the Participant with respect to the subject matter hereof and supersede in their entirety all prior undertakings and agreements of the Company and the Participant with respect to the subject matter hereof, and this Agreement may not be modified adversely to the Participant's interest except by means of a writing signed by the Company and Participant. This Agreement shall be governed by and construed in accordance with the General Corporation Law of the State of Delaware, as to matters within the scope thereof, and the internal laws of the State of North Carolina (without reference to conflict of law provisions), as to all other matters.

(h) Amendment. This Agreement may be amended or modified only by a written instrument executed by both the Company and the Participant.

(i) Participant's Acknowledgments. The Participant acknowledges that the Participant: (i) has read this Agreement; (ii) has been represented in the preparation, negotiation, and execution of this Agreement by legal counsel of the Participant's own choice or has voluntarily declined to seek such counsel; (iii) understands the terms and consequences of this Agreement; (iv) is fully aware of the legal and binding effect of this Agreement; and (v) understands that the law firm of Hutchison PLLC, is acting as counsel to the Company in connection with the transactions contemplated by the Agreement, and is not acting as counsel for the Participant.

[Remainder of Page Intentionally Left Blank]

Exhibit A

INNOVATE BIOPHARMACEUTICALS INC.

Joint Escrow Instructions

Corporate Secretary
Innovate Biopharmaceuticals Inc.

Dear Madam or Sir:

As Escrow Agent for Innovate Biopharmaceuticals Inc., a Delaware corporation (the "**Company**"), and its successors in interest under the Restricted Stock Purchase Agreement, and related Summary of Restricted Stock Purchase, each of even date herewith (the "**Agreement**"), to which a copy of these Joint Escrow Instructions is attached, and the undersigned person ("**Holder**"), you are hereby authorized and directed to hold the documents delivered to you pursuant to the terms of the Agreement in accordance with the following instructions:

1. Appointment. Holder irrevocably authorizes the Company to deposit with you any certificates evidencing the Shares (as defined in the Agreement) to be held by you hereunder and any additions and substitutions to said Shares. For purposes of these Joint Escrow Instructions, "**Shares**" shall be deemed to include any additional or substitute property. Holder does hereby irrevocably constitute and appoint you as his attorney-in-fact and agent for the term of this escrow to execute with respect to such Shares all documents necessary or appropriate to make such Shares negotiable and to complete any transaction herein contemplated. Subject to the provisions of this Section 1 and the terms of the Agreement, Holder shall exercise all rights and privileges of a stockholder of the Company while the Shares are held by you.

2. Closing of Repurchase.

(a) Upon any repurchase by the Company of the Shares pursuant to the Agreement, the Company shall give to Holder and you a written notice specifying the number of Shares to be repurchased, the purchase price for the Shares, as determined pursuant to the Agreement, and the time for a closing hereunder (the "**Closing**") at the principal office of the Company. Holder and the Company hereby irrevocably authorize and direct you to close the transaction contemplated by such notice in accordance with the terms of said notice.

(b) At the Closing, you are directed (i) to date the stock assignment form or forms necessary for the transfer of the Shares, (ii) to fill in on such form or forms the number of Shares being transferred, and (iii) to deliver the same, together with the certificate or certificates evidencing the Shares to be transferred, to the Company against the simultaneous delivery to you of the purchase price for the Shares being repurchased pursuant to the Agreement.

3. Withdrawal. The Holder shall have the right to withdraw from this escrow any of the Shares as to which the Right of Repurchase (as defined in the Agreement) has terminated or expired.

4. Duties of Escrow Agent.

(a) Your duties hereunder may be altered, amended, modified or revoked only by a writing signed by all of the parties hereto.

(b) You shall be obligated only for the performance of such duties as are specifically set forth herein and may rely and shall be protected in relying or refraining from acting on any instrument reasonably believed by you to be genuine and to have been signed or presented by the proper party or parties. You shall not be personally liable for any act you may do or omit to do hereunder as Escrow Agent or as attorney-in-fact of Holder while acting in good faith and in the exercise of your own good judgment, and any act done or omitted by you pursuant to the advice of your own attorneys shall be conclusive evidence of such good faith.

(c) You are hereby expressly authorized to disregard any and all warnings given by any of the parties hereto or by any other person or entity, excepting only orders or process of courts of law, and are hereby expressly authorized to comply with and obey orders, judgments or decrees of any court. If you are uncertain of any actions to be taken or instructions to be followed, you may refuse to act in the absence of an order, judgment or decrees of a court. In case you obey or comply with any such order, judgment or decree of any court, you shall not be liable to any of the parties hereto or to any other person or entity, by reason of such compliance, notwithstanding any such order, judgment or decree being subsequently reversed, modified, annulled, set aside, vacated or found to have been entered without jurisdiction.

(d) You shall not be liable in any respect on account of the identity, authority or rights of the parties executing or delivering or purporting to execute or deliver the Agreement or any documents or papers deposited or called for hereunder.

(e) You shall be entitled to employ such legal counsel and other experts as you may deem necessary properly to advise you in connection with your obligations hereunder and may rely upon the advice of such counsel.

(f) Your rights and responsibilities as Escrow Agent hereunder shall terminate if (i) you cease to be Secretary of the Company or (ii) you resign by written notice to each party. In the event of a termination under clause (i), your successor as Secretary shall become Escrow Agent hereunder; in the event of a termination under clause (ii), the Company shall appoint a successor Escrow Agent hereunder.

(g) If you reasonably require other or further instruments in connection with these Joint Escrow Instructions or obligations in respect hereto, the necessary parties hereto shall join in furnishing such instruments.

(h) It is understood and agreed that if you believe a dispute has arisen with respect to the delivery and/or ownership or right of possession of the securities held by you hereunder, you are authorized and directed to retain in your possession without liability to anyone all or any part of said securities until such dispute shall have been settled either by mutual written agreement of the parties concerned or by a final order, decree or judgment of a court of competent jurisdiction after the time for appeal has expired and no appeal has been perfected, but you shall be under no duty whatsoever to institute or defend any such proceedings.

(i) These Joint Escrow Instructions set forth your sole duties with respect to any and all matters pertinent hereto and no implied duties or obligations shall be read into these Joint Escrow Instructions against you.

(j) The Company shall indemnify you and hold you harmless against any and all damages, losses, liabilities, costs, and expenses, including attorneys' fees and disbursements, (including without limitation the fees of counsel retained pursuant to Section 4(e) above, for anything done or omitted to be done by you as Escrow Agent in connection with this Agreement or the performance of your duties hereunder, except such as shall result from your gross negligence or willful misconduct.

5. Notice. Any notice required or permitted hereunder shall be given in writing and shall be deemed effectively given upon personal delivery or upon deposit in the United States Post Office, by registered or certified mail with postage and fees prepaid, addressed to each of the other parties thereunto entitled at the following addresses, or at such other addresses as a party may designate by ten days' advance written notice to each of the other parties hereto.

COMPANY: Notices to the Company shall be sent to the address set forth in the salutation hereto, Attn: President

HOLDER: Notices to Holder shall be sent to the address set forth below Holder's signature below.

ESCROW AGENT: Notices to the Escrow Agent shall be sent to the address set forth in the salutation hereto.

6. Miscellaneous.

(a) By signing these Joint Escrow Instructions, you become a party hereto only for the purpose of said Joint Escrow Instructions, and you do not become a party to the Agreement.

(b) This instrument shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

Very truly yours,

INNOVATE BIOPHARMACEUTICALS INC.:

By: _____

Name: _____

HOLDER:

By: _____

Name: _____

Address: _____

_____

ESCROW AGENT:

By: _____

Name: _____

Date: _____

Exhibit B

INNOVATE BIOPHARMACEUTICALS INC.

STOCK ASSIGNMENT SEPARATE FROM CERTIFICATE

FOR VALUE RECEIVED, I hereby sell, assign and transfer _____ shares of common stock, of Innovate Biopharmaceuticals Inc., a Delaware corporation (the "**Company**"), standing in my name on the books of the Company represented by Certificate(s) Number _____ herewith, to _____ and do hereby irrevocably constitute and appoint Hutchison PLLC to transfer the said stock on the books of the Company with full power of substitution in the premises.

Dated: _____

HOLDER:

_____
(Signature)

_____
(Print Name)

Exhibit 10.17

SEPARATION AGREEMENT AND RELEASE OF CLAIMS

This Separation Agreement and Release of Claims (the "Agreement") is entered into by and between David Olert (hereinafter "Employee") and Monster Digital, Inc., its officers, directors, employees, agents and affiliates (hereinafter "the Company").

Recitals

Whereas, the Company desires to provide the Employee separation compensation to assist him/her in the transition resulting from his/her termination of employment from the Company.

Whereas, the Employee agrees, in exchange for such separation compensation, to execute this Agreement and waive and release any and all claims that he/she may have against the Company.

This settlement does not constitute an admission of any kind by the Company. Employee acknowledges that he/she has received all monies and other benefits due him/her as a result of his/her employment with and separation from the Company.

Now, therefore, in consideration of the mutual promises contained in this Agreement, and for other good and valuable consideration, the parties agree as follows:

Agreement

1. Separation Pay. Employee's separation from the Company is effective January 26, 2018. The Company agrees that, provided Employee: (i) returns the original fully executed Agreement to the Company by or before the end of the Review Period as set forth in Section 5 and (ii) does not revoke this Agreement per Section 5, the Company will provide Employee an amount equal to zero weeks of his/her base wages as separation pay in consideration of the promises set forth herein. The payment will be paid in a lump sum, as soon as administratively possible, following Employee's termination date in accordance with the Company's normal payroll procedures, and is subject to all applicable federal and state taxes.

2. Taxes. Notwithstanding the tax deductions set forth in Section 1 above, Employee shall pay in full when due, and shall be solely responsible for, any and all federal, state, or local income taxes that are or may be assessed against him/her relating to the separation payment received by Employee pursuant to this Agreement, as well as all interest or penalties that may be owed in connection with such taxes. Employee is not relying on any representations or conduct of the Company with respect to the adequacy of the withholdings and understands his/her responsibility to pay taxes associated with the separation pay.

3. (a). Confidential and Proprietary Information. Employee understands that, during the course of his/her employment with the Company, he/she was given access to and provided with substantial confidential and proprietary information of the Company which includes, but is not limited to, all information related to the Company's customers and its business dealings with such customers, the services provided to customers by the Company, and the Company's methodology for providing said services ("Confidential and Proprietary Information"). The Company is the sole owner of all such Confidential and Proprietary information and Employee expressly understands and agrees that he/she may not, under any circumstances to the fullest extent permitted by applicable law, whether directly or indirectly, disclose the Company's Confidential and/or Proprietary information to any person or entity at any time or use any of the Company's Confidential and/or Proprietary information for any purpose without the express written authorization of the Company.

(b) Employee agrees that, for a period of one (1) year following his/her execution of this Agreement, he/she will not, directly or indirectly, on his/her own behalf, or on behalf of any other individual, association or entity, use the Confidential or Proprietary information of the Company to (i) solicit, induce, or contact any current or prospective customer of the Company of which he/she has knowledge as a result of his/her employment with the Company; (ii) encourage any current or prospective customers or suppliers of the Company of which he/she has knowledge as a result of his/her employment with the Company to stop using the facilities or services of the Company, or (iii) encourage any current or prospective customers or suppliers of the Company of which he/she has knowledge as a result of his/her employment with the Company to use the facilities or services of any competitor of the Company.

(c) For a period of one year from the date that Employee is no longer employed by the Company, Employee shall not take any actions to, nor shall he/she assist any entity in, recruiting any other employee who worked for or was affiliated with the Company at any point while Employee was employed by the Company. This includes, but is not limited to: (i) identifying to such successor employer or its agents or such other entity the person or persons who have special knowledge concerning the Company's processes, methods or confidential affairs; and (ii) commenting to the successor employer or its agents or such other entity about the quantity of work, quality of work, special knowledge, or personal characteristics of any person who is still employed at the Company. Employee also agrees that Employee will not provide such information set forth in (i) and (ii) above to a prospective employer during interviews preceding possible employment.

4. Release of Known and Unknown Claims by Employee. Employee agrees unconditionally and forever to release and discharge the Company and its affiliated business entities, their respective current and former stockholders, officers, directors, employees, representatives, attorneys, agents and assigns (collectively, "Released Parties"), from any and all claims, actions, causes of action, demands, rights, or damages of any kind or nature which he/she may now have, or ever have, whether known or unknown, including any claims, causes of action or demands of any nature arising out of or in any way relating to his/her employment with, or separation from the Company on or before the date of the execution of this Agreement.

This release specifically includes, but is not limited to, any claims for wages, bonuses, benefits, vacation pay, severance pay or other compensation of any sort, wrongful discharge, retaliation, breach of implied contract, breach of implied covenant of good faith and fair dealing, negligence, negligent hiring, retention or supervision, defamation, unlawful efforts to prevent relationship, violation of constitutional rights, discrimination or harassment on the basis of race, color, sex, sexual orientation, national origin, religion, age (including but not limited to claims arising under the Age Discrimination in Employment Act and Older Worker Benefit Protection Act, 29 U.S.C. § 621, et seq.), disability, medical condition or marital status, and/or violation of any statutes, rules, regulations or ordinances, whether federal, state or local, including, but not limited to, Title VII of the Civil Rights Act of 1964, the California Fair Employment and Housing Act, the California Family Rights Act, and qui tam actions pursuant to any federal, state or local statute, rule, regulation or ordinance.. Notwithstanding the foregoing, nothing in this Agreement shall prevent Employee from filing a charge with a government agency or cooperating in an investigation conducted by a government agency. However, Employee agrees except with respect to proceedings before the Securities and Exchange Commission, he/she is waiving his right to any monetary damages or other equitable relief as a result of any such proceedings.

Employee further agrees knowingly to waive the provisions and protections of Section 1542 of the California Civil Code, which reads:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH, IF KNOWN BY HIM OR HER, MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

5. ADEA Waiver and Revocation. Without detracting in any respect from any other provision of this Agreement:

(a) Employee agrees that this Agreement constitutes a knowing and voluntary waiver and release of all rights or claims Employee has or may have against the any of the Released Parties, including, but not limited to, all rights or claims for age discrimination or retaliation arising under the Age Discrimination in Employment Act)(“ADEA”). Employee understands that, by entering into this Agreement, Employee does not waive rights or claims that may arise after the date Employee signs this Agreement, including without limitation any rights or claims that Employee may have to secure enforcement of the terms and conditions of this Agreement. Company has advised Employee in writing of his/her right to consult with an attorney prior to executing this Agreement. Employee acknowledges that he/she was informed that he/she has a full twenty-one (21) days in which to review and consider this Agreement (“Review Period”) and to consult with an attorney regarding the terms and effect of this Agreement. To the extent that Employee chooses to sign this Agreement in less than twenty-one (21) days, Employee acknowledges that he/she had sufficient time to consider the Agreement and to consult with counsel and that Employee does not desire additional time.

(b) Employee may revoke this Agreement within seven (7) days from the date he/she signs this Agreement, in which case this Agreement will be null and void and of no force or effect on either Company or Employee. Any revocation must be in writing and sent to David Olert, 2655 First Street, Suite 250, Simi Valley, CA 93065, on or before the close of business on the seventh day after this Agreement is executed by Employee.

6. Non-Disclosure of This Agreement. Employee agrees not to disclose the existence of this Agreement or any of its terms to anyone other than his/her attorneys, accountants and immediate family members, or where compelled by an order of a court of competent jurisdiction or a subpoena issued under the authority thereof. Employee further agrees to keep this Agreement and all of its terms strictly confidential and agrees that he/she will inform any such attorneys, accountants and immediate family members about this confidentiality provision and that they will agree to be bound by it. Further, Employee agrees that neither he/she nor his/her representatives or family members will reveal any confidential information about the Company, its operations, its client base, its prospects, its executives or its employees to any third party.

7. Knowing and Voluntary. Employee represents and agrees that, prior to the execution of this Agreement, Employee has had the opportunity to discuss the terms of this Agreement with legal counsel of his/her choosing. Employee affirms that no promise or inducement was made to cause him/her to enter into this Agreement, other than the separation pay promised to Employee in this Agreement. Employee further confirms that he/she has not relied upon any other statement or representation by anyone other than what is in this Agreement as a basis for his/her agreement.

8. Entire Agreement. This Agreement constitutes the entire agreement between Employee and the Company concerning the terms of Employee's employment with and separation from the Company and the compensation related thereto. No amendments to this Agreement will be valid unless written and signed by Employee and an Officer of the Company. This Agreement shall be binding upon both parties' heirs, representatives and successors. This Agreement shall be construed under the laws of the State of California, both procedural and substantive.

9. Arbitration. Any and all disputes, controversies or claims arising under or in any way relating to the interpretation, application or enforcement of this Agreement, Employee's employment with the Company, any claim for benefits, or Employee's separation of employment from the Company, including without limitation any claim by Employee that he/she was fraudulently induced to enter into this Agreement, or claims relating to the general validity or enforceability of this Agreement, shall be settled by final and binding arbitration as described in more detail in this Section. Any dispute submitted to arbitration pursuant to this Section shall be determined by arbitration in accordance with the applicable rules of the American Arbitration Association, which can be obtained directly from AAA (www.adr.org). The parties to any arbitration shall mutually select a single arbitrator to hear the matter; provided that if the parties are unable to agree, the arbitrator shall be selected by AAA. The arbitration shall be held in the County where Employee was last employed by the Company. Judgment upon any arbitration award may be entered by any state or federal court having jurisdiction thereof. The prevailing party shall be entitled to reasonable costs and attorney's fees, as allowed by law. The parties intend this arbitration provision to be valid, enforceable, irrevocable and construed as broadly as possible.

10. Severability. If any portion of this Agreement is found to be illegal or unenforceable, such action shall not affect the validity or enforceability of the remaining sections or subsections of this Agreement.

11. Governing Law. This Agreement shall be construed under the laws of the State of California, both procedural and substantive.

12. Waiver. The failure to enforce any provision of this Agreement shall not be construed to be a waiver of such provision or to affect the validity of this Agreement or the right of any party to enforce this Agreement.

13. Ambiguities. Both parties have participated in the negotiation of this Agreement and, thus, it is understood and agreed that the general rule that ambiguities are to be construed against the drafter shall not apply to this Agreement. In the event that any language of this Agreement is found to be ambiguous, each party shall have an opportunity to present evidence as to the actual intent of the parties with respect to any such ambiguous language.

EMPLOYEE ACKNOWLEDGES AND AGREES HE/SHE HAS CAREFULLY READ AND VOLUNTARILY SIGNS THIS AGREEMENT, THAT HE/SHE HAS BEEN REPRESENTED BY COUNSEL AND HAD SUFFICIENT OPPORTUNITY TO CONSULT WITH AN ATTORNEY OF HIS/HER CHOICE, AND THAT HE/SHE SIGNS THIS AGREEMENT WITH THE INTENT OF RELEASING AFL AND THE RELEASED PARTIES FROM ANY AND ALL CLAIMS.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

The undersigned agree to the terms of this Agreement and voluntarily enter into it with the intent to be bound thereby.

Dated: January 26, 2018

/s/ David Olert
(Employee Signature)

Dated: January 25, 2018

Monster Digital, Inc.

/s/ David Olert
By: David Olert

AGREEMENT FOR CONSULTING SERVICES

This **CONSULTING AGREEMENT** (this "Agreement") is made by and among **INNOVATE BIOPHARMACEUTICALS, INC.** ("COMPANY"), a Delaware corporation, with its principal place of business at 8480 Honeycutt Road, Suite 120, Raleigh, NC 27615, and **DAVID OLERT** ("CONSULTANT") effective as of this 17th day of February, 2018. Capitalized terms used by not defined herein shall have the meanings ascribed to such terms in the Agreement and Plan of Merger and Reorganization by and among Monster Digital, Inc. (now Innovate Biopharmaceuticals, Inc.), a wholly owned subsidiary of Monster Digital, Inc., Monster Merger Sub, Inc., a Delaware corporation, and Innovate Biopharmaceuticals Inc. (now IB Pharmaceuticals Inc.), a Delaware corporation (the "MERGER AGREEMENT").

WITNESSETH

WHEREAS, prior to the completion of the MERGER AGREEMENT, CONSULTANT served as the Chief Financial Officer of Monster Digital, Inc.;

WHEREAS, COMPANY desires and may in the future desire to engage CONSULTANT to perform the consulting services described herein; and

WHEREAS, CONSULTANT desires to render professional consulting services to COMPANY in the solution of agreed upon problems and the performance of agreed upon tasks as hereinafter provided;

NOW, THEREFORE, in consideration of the premises and of the mutual promises and covenants herein contained, the parties hereto agree as follows:

1. Consulting Services. COMPANY hereby offers to engage CONSULTANT, and CONSULTANT hereby accepts engagement by COMPANY, to perform the professional and consulting services identified on Exhibit A hereto. Services that CONSULTANT agrees to perform hereunder shall be performed subject to and in accordance with this Agreement. CONSULTANT shall use commercially reasonable efforts to keep COMPANY advised of the progress of the services, to permit representatives of COMPANY to inspect from time to time and at reasonable times such results of said consulting services as are susceptible of inspection, and to keep records of time worked and out-of-pocket expenses incurred that the parties have agreed in writing shall be reimbursed by COMPANY and to make such records available to COMPANY at reasonable times and on reasonable advance notice. CONSULTANT shall report to Joanne Zach and such other persons at COMPANY as designated by COMPANY.

2. Payment of Consulting Fees/Reimbursement of Expenses.

(a) In consideration for CONSULTANT'S acceptance of this Agreement and the performance by CONSULTANT of the professional consulting services as contemplated hereby, COMPANY shall pay CONSULTANT consulting fees based on each hour of consulting services performed by CONSULTANT at the rate of one-hundred, twenty-five dollars ($125) per hour, payable in accordance with the provisions of this Agreement. In addition, upon CONSULTANT's continued and satisfactory service through the end of the Initial Term, including through the filing of the Form 10-K, CONSULTANT shall be eligible to be paid the sum of ten-thousand dollars ($10,000) as a completion bonus (the "Completion Bonus").

(b) COMPANY shall reimburse CONSULTANT for all reasonable and customary out-of-pocket expenses incurred by CONSULTANT in performing his professional services hereunder, provided that such expenses are pre-approved in writing by COMPANY and CONSULTANT provides COMPANY with supporting receipts and documentation for such expenses that is satisfactory to COMPANY. COMPANY shall reimburse CONSULTANT for such expenses within thirty (30) days of receipt of adequate documentation.

(c) CONSULTANT shall submit to the COMPANY a statement and invoice detailing the services provided and the time incurred by the fifth day of the month after the month in which services are rendered. COMPANY shall make payment by check or wire transfer delivered to CONSULTANT within thirty (30) days after receipt of CONSULTANT's invoice. The COMPANY shall pay the Completion Bonus, if earned, in lump sum within fifteen (15) days of the end of the Initial Term.

3. Confidentiality; Proprietary Rights. The terms of that certain Confidentiality Agreement dated February 17, 2018, between COMPANY and CONSULTANT with respect to confidential information, proprietary information and intellectual property rights] shall continue in full force and effect and apply to CONSULTANT and his provision of services under this Agreement.

4. Term. Unless earlier terminated as hereinafter provided, the term of CONSULTANT'S engagement under this Agreement shall begin as of the date of the Separation, and continue until the date on which COMPANY files its Form 10-K of the fiscal year ended December 31, 2017 (the "Initial Term"), with such term automatically renewing for successive three month periods thereafter unless earlier terminated as provided herein (the "Term").

5. Termination. COMPANY reserves the right to discontinue at any time any work with respect to which CONSULTANT shall have been performing consulting services hereunder by giving CONSULTANT written notice of such discontinuance. In addition, immediately if COMPANY materially breaches this Agreement, or upon 45 days' prior written notice following completion of the Initial Term, CONSULTANT may terminate this Agreement. The failure by COMPANY to pay when due any amounts payable to CONSULTANT hereunder shall constitute a material breach of this Agreement. In the event of the discontinuance of services by COMPANY or termination by CONSULTANT (as the case may be) of this Agreement as hereinbefore provided, COMPANY shall be obligated to pay CONSULTANT (in accordance with the provisions for and limitations with respect to payment set forth herein) all amounts payable to CONSULTANT hereunder up to and including the date on which CONSULTANT receives actual notice of such discontinuance by COMPANY or the date of such termination by CONSULTANT, whichever is applicable. COMPANY'S obligations hereunder shall survive the termination of this Agreement.

6. Relationship of the Parties. The business relationship between CONSULTANT and COMPANY shall be that of independent contractor and not employer-employee or principal-agent. CONSULTANT is not and will not be an employee of COMPANY under the meaning of any federal or state unemployment or insurance laws or workers' compensation laws or otherwise, and CONSULTANT shall not be entitled to or shall not be provided any medical coverage, insurance of any kind, vacation pay, pension benefits or any other type of employee benefit by COMPANY. Neither party shall have the authority to legally bind the other in contract, debt or otherwise or to represent itself as an agent, employee or in any other capacity of the other.

7 Taxes. CONSULTANT will be responsible for the payment of taxes on CONSULTANT's entire compensation under this Agreement, including income taxes, employment and unemployment, Medicare and social security taxes and other or similar taxes required by application of law. COMPANY shall not withhold any taxes in connection with the compensation paid to CONSULTANT hereunder. Such payments shall be the sole responsibility of CONSULTANT, and CONSULTANT agrees to file all required forms and make all required payments appropriate to CONSULTANT's tax status when and as they become due. CONSULTANT agrees to indemnify COMPANY, and each of its officers, directors and employees from and against all payments, losses, costs, liability, expenses, damages, fines, penalties and judgments (including, without limitation, actual attorneys' fees and expenses) incurred by COMPANY or any of its officers, directors or employees as a result of a failure by CONSULTANT (a) to pay all the taxes due in connection with the compensation paid to CONSULTANT under this Agreement, (b) to respond to any administrative inquiry concerning CONSULTANT's payment of such taxes, or (c) to defend against any administrative or judicial proceeding with respect to CONSULTANT's payment of such taxes.

8. Entire Agreement/Binding Effect. This Agreement contains the complete understanding between the parties with respect to the subject matter hereof, and supersedes all other agreements, whether written or oral, between the parties concerning such subject matter; provided, however, that for the avoidance of doubt CONSULTANT acknowledges and agrees that the execution of this Agreement does not alter his obligations under any other agreements (including, without limitation, any employment, severance, confidentiality or other similar agreements) between CONSULTANT and COMPANY. This Agreement shall be binding on and inure to the benefit of the parties and their respective successors and permitted assigns. This Agreement shall not amend in any way the Separation Agreement and Release of Claims that CONSULTANT and COMPANY entered into on January 26, 2018. In addition, the parties intend that CONSULTANT incurred a "Separation from Service" within the meaning of Section 409A of the Internal Revenue Code (the "Code") from COMPANY on the Separation date, and that the parties do not intend that the level of services provided by CONSULTANT under this Agreement, or otherwise, will alter or affect such Separation from Service.

9. Modifications. No waiver or modification of this Agreement or any provision hereof shall be valid and no evidence of waiver or modification shall be offered or received in evidence in any proceeding, arbitration or litigation between the parties hereto arising out of or affecting this Agreement or the rights or obligations of the parties hereunder, unless such waiver or modification is in writing duly signed by both parties.

10. Assignment. This Agreement is not assignable by CONSULTANT or COMPANY without the prior written consent of the other party; provided, however, that COMPANY may assign this Agreement to any affiliate of COMPANY without the consent of CONSULTANT. Any assignment in violation of this Section 10 shall be void.

11. Governing Law; Jurisdiction. This Agreement shall be interpreted and construed in accordance with the laws of the State of North Carolina. Any and all claims, controversies and causes of action arising out of or relating to this Agreement, whether sounding in contract, tort or statute, shall be governed by the laws of the State of North Carolina, including its statutes of limitations, without giving effect to any conflict-of-laws or other rule that would result in the application of the laws of a different jurisdiction. The parties consent and agree to submit and be subject to the exclusive jurisdiction of the Federal and State courts located in Wake County, North Carolina for the resolution of all claims, controversies and causes of action arising out of or relating to this Agreement.

12. Notices. All notices and other communications under this agreement shall be in writing and shall be given to the parties at their respective addresses set forth below, or to such other address or telecopy number as either party may designate by written notice in the manner provided herein, and shall be sent by (a) hand delivery, (b) certified mail, return receipt requested, postage prepaid, (c) a recognized overnight delivery service, or (d) telecopy or other means of facsimile or by email.

IF TO CONSULTANT:
David Olert
PO box 1401
Thousand Oaks, CA 91358
Dolert@hotmail.com

IF TO COMPANY:
Innovate Biopharmaceuticals, Inc.
8480 Honeycutt Road, Suite 120
Raleigh, NC 27615
Attn: Kendyle Woodard
Email: *kwoodard@innovatebiopharma.com*

13. Representations of CONSULTANT. CONSULTANT represents that it is under no obligation, contractual or otherwise, to any other person, institution or other entity that would prohibit the rendering of services called for in this Agreement or that would prohibit the payments for professional services in the amount and the manner as set forth herein.

14. No Waiver. No failure or delay by a party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof or the exercise of any right, power or privilege hereunder.

15. If any term or provision of this Agreement is held to by a court of competent jurisdiction to be invalid, void or unenforceable, the remainder of the terms and provisions of this letter agreement shall remain in full force and effect and shall in no way be affected, impaired or invalidated.

16. Survival. In addition to the provisions of this Agreement that, by their terms, survive the termination or expiration of this Agreement, Sections 7–15, and COMPANY'S obligation to pay CONSULTANT'S fees and expenses as provided herein, shall survive the termination or expiration of this Agreement.

[*Signature page follows*]

IN WITNESS WHEREOF the parties hereto have caused this Agreement to be duly executed as of the date set forth above.

INNOVATE BIOPHARMACEUTICALS, INC.		**DAVID OLERT**	
By:	/s/ Kendyle Woodard	By:	/s/ David Olert
Name:	Kendyle Woodard	Name:	David Olert
Title:	Director	Title:	Consultant

EXHIBIT A

CONSULTANT will perform such services related to the preparation of COMPANY's financial statements, filings with the Securities and Exchange Commission, filings with the Nasdaq Stock Market and other related matters as requested by COMPANY from time to time, including, without limitation, preparing specified sections of COMPANY's 2017 Annual Report on Form 10-K, coordinating with COMPANY's independent auditor and other related matters. CONSULTANT acknowledges and agrees that the provision of these services and the completion of these items in accordance with the timelines provided by COMPANY is critical so that COMPANY is able to meet its regulatory and contractual obligations.

Exhibit 10.20

EXECUTIVE EMPLOYMENT AGREEMENT

THIS EXECUTIVE EMPLOYMENT AGREEMENT (the "**Agreement**"), is entered into as of November 2, 2015 (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Christopher P. Prior, Ph.D. (the "**Executive**"), an individual residing in Delaware County, Pennsylvania.

WITNESSETH:

WHEREAS, the Company wishes to employ the Executive, and the Executive desires to accept employment with the Company, upon the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing, of the mutual promises herein, and of other good and valuable consideration, including the employment of the Executive by the Company and the compensation to be received by the Executive from the Company from time to time, and specifically the compensation to be received by the Executive pursuant to Section 4 hereof, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending legally to be bound, hereby agree as follows:

1. Employment. As of the Effective Date, the Company hereby employs the Executive and the Executive hereby accepts employment as the Chief Executive Officer ("**CEO**") of the Company upon the terms and conditions of this Agreement. The Executive and shall report to the Board of Directors of the Company (the "**Board**").

2. Duties. The Executive shall faithfully perform all duties of the Company related to the position or positions held by the Executive, including but not limited to all duties set forth in this Agreement and/or in the Bylaws of the Company related to the position or positions held by the Executive and all additional duties that are prescribed from time to time by the Board or other designated officers of the Company. The Executive shall devote the Executive's full time and attention to the performance of the Executive's duties and responsibilities on behalf of the Company and in furtherance of its best interests; provided, however, that the Executive, subject to the Executive's obligations hereunder, shall also be permitted to make personal investments, perform reasonable volunteer services and, with the prior consent of the Company, serve on outside boards of directors for non-profit corporations. The Executive shall comply with all Company policies, standards, rules and regulations (the "**Company Policies**") and all applicable government laws, rules and regulations that are now or hereafter in effect. The Executive acknowledges receipt of copies of all written Company Policies that are in effect as of the date of this Agreement.

3. Term. Unless earlier terminated as provided herein, the initial term of this Agreement shall commence on the Effective Date and shall continue for three years from the Minimum Financial Milestone Event (as defined below) (the "**Term**"). Thereafter, this Agreement shall automatically renew on a year-to-year basis on the same terms and conditions as set forth herein unless: (a) earlier terminated or amended as provided herein or (b) either party gives written notice of non-renewal at least 60 days prior to the end of the Term or any renewal term thereafter. The initial term and all renewals thereof are referred to as the "**Term**."

4. Compensation. During the Term, as compensation for the services rendered by the Executive under this Agreement, the Executive shall be entitled to receive the following (all payments are subject to applicable withholdings):

(a) Base Salary. Upon the occurrence of the Minimum Financial Milestone Event (as defined below), the Executive shall be paid an annual salary in the amount of $240,000, which shall be payable in accordance with the then-current payroll schedule of the Company (the "**Base Salary**"), less all applicable taxes and withholdings; *provided*, however, that the Executive shall be paid minimum wage in accordance with applicable state law until such time as the Minimum Financial Milestone Event has occurred. From and after the date of the Minimum Financial Milestone Event, the Executive shall be entitled to payment of the Base Salary in accordance with the then-current payroll schedule of the Company. Upon the occurrence of the Second Financial Milestone Event (as defined below), the Executive's Base Salary shall be increased to $300,000, which shall be paid in accordance with the then-current payroll schedule of the Company commencing on the first regularly scheduled payroll date of the Company after the Second Minimum Financial Milestone Event has occurred. The Executive's salary may be increased from time to time by the Board. Notwithstanding anything to the contrary, the Base Salary may be reduced if the Board approves and implements an equal percentage reduction in the base salaries of all of the Company's executive officers, but in no event will such reduction be greater than 15% of the Base Salary. A reduction in the Executive's Base Salary in accordance with the immediately preceding sentence shall not constitute a substantial reduction in salary as described at paragraph 5(b)(i)(A) of this Agreement.

For the purposes of this Agreement, the "**Minimum Financial Milestone Event**" shall mean the sale by the Company of its Equity Securities in a bona fide equity financing following the Effective Date in which the Company receives gross proceeds of not less than $5,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. "**Equity Securities**" means the Company's common stock or preferred stock issued to one or more third parties for bona fide equity financing purposes. The "**Second Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event) following the Effective Date of this Agreement in which the Company receives aggregate gross proceeds of at least $30,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. For purposes of clarity, the amount of the Minimum Financial Milestone Event shall be included in calculating the Second Milestone Event.

(b) Bonuses.

(i) Upon the occurrence of the Minimum Financial Milestone Event (as defined above) provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $60,000, less applicable withholdings, which shall be paid within 30 days of the occurrence of the Minimum Financial Milestone Event.

(ii) Upon the occurrence of the Second Minimum Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $175,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Second Minimum Financial Milestone Event. In the event a Second Minimum Financial Event is the initial fundraising, the Executive shall be entitled to payment of both bonuses specified under subparts (i) above this subpart (ii), and both bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Second Minimum Financial Milestone Event.

For the purposes of subparts (i) and (ii) above, the Executive shall only be paid the bonuses specified therein if: (A) the Executive is employed by the Company on the effective date of the occurrence of the Minimum Financial Milestone Event and/or Second Minimum Financial Milestone Event, as appropriate, or has been terminated without Cause prior to such date. For purposes of clarity, if the Executive is not employed by the Company upon the applicable milestone or has been terminated for Cause (as defined herein) prior to the occurrence of the applicable milestone event, the Executive shall have no right to the payment of the bonus specified under subpart (i) or subpart (ii) hereof.

(iii) The Executive shall be eligible to participate in all bonus or similar incentive plans adopted by the Board. The amount awarded, if any, to the Executive under any bonus or incentive plan shall be in the discretion of the Board or any committee administering such plan, based on its assessment of the Executive's and the Company's performance during the relevant period. If a Bonus is awarded, unless otherwise specifically provided by the Board or committee administering such plan, it shall be paid within 30 days of December 31st in the year following the year in which the Bonus was awarded.

(c) Equity. Following the completion of the Minimum Financial Milestone Event, the Executive shall be eligible for an annual grant of restricted stock (the "**Equity Grant**") for each year of service during the Term, which grant shall be made at the then-current fair market value of such restricted stock on the date of grant, subject to (i) the Executive's achievement of the agreed-upon milestones set forth on Exhibit A in the applicable calendar year, which milestones may be modified on an annual basis commencing in the year 2016; (ii) the approval of the grant by the Board; and (iii) the Executive's continued employment by the Company until such time as the Equity Grant is made. If an Equity Grant is made by the Board, it shall be made within 45 days of December 31st of the applicable calendar year. The terms and conditions of the Equity Grant shall be governed by a Restricted Stock Purchase Agreement in a form mutually acceptable to the Executive and the Company and shall be governed by the Company's 2015 Stock Incentive Plan, which shall be approved and adopted by the Company before the Equity Grant is made. It is understood that each Equity Grant shall be subject to a Right of Repurchase in favor of the Company, which Right of Repurchase shall be subject to the Company's standard vesting schedule unless otherwise agreed whereby the Company's Right of Repurchase shall lapse with respect to 25% of the restricted stock on the one year anniversary of the date of grant and with respect to an additional 1/48 each month on the corresponding day of the month thereafter, until all of the restricted stock has been released from restrictions on the fourth anniversary of the date of grant, subject to Executive continuing perform services through each such date. Each Equity Grant shall provide that the Company's Right of Repurchase shall lapse 100% upon a Change in Control, as such term is defined in the Restricted Stock Purchase Agreement.

(d) Benefits. The Executive shall be entitled to receive those benefits provided from time to time to other executive employees of the Company, in accordance with the terms and conditions of the applicable plan documents; provided that the Executive meets the eligibility requirements thereof. All such benefits are subject to amendment or termination from time to time by the Company without the consent of the Executive or any other employee of the Company.

(e) Paid Time Off. The Executive shall be entitled to four weeks of paid time off ("**PTO**") (prorated for partial calendar years) to be taken at such times as may be approved by the Board. PTO earned in one calendar year may not be used in any subsequent calendar year. Upon the termination of the Executive's employment with the Company, the Executive shall be paid for any accrued and used PTO (less standard employment related withholdings and dedcutions).

(f) Business Expenses. The Company shall pay, or reimburse the Executive for, all reasonable expenses incurred by the Executive directly related to conduct of the business of the Company; provided that, the Executive complies with the Company's policies for the reimbursement or advancement of business expenses that are now or hereafter in effect.

5. Termination. This Agreement and the Executive's employment by the Company shall or may be terminated, as the case may be, as follows:

(a) Termination upon Expiration of the Term. This Agreement and the Executive's employment by the Company shall terminate upon the expiration of the Term in the event notice of non-renewal is provided according to the terms of Section 3.

(b) Termination by the Executive. The Executive may terminate this Agreement and his employment by the Company:

(i) for "Good Reason" (as defined herein). For purposes of this Agreement, "**Good Reason**" shall mean, the existence, without the consent of the Executive, of any of the following events: (A) the Executive's duties and responsibilities or salary are substantially reduced or diminished; (B) the Company materially breaches its obligations under this Agreement, including the failure of the Company to pay the Executive any Base Salary that becomes due and payable within 30 days after the Employee has given the Company written notice thereof; or (C) the Executive's place of employment is relocated by more than 50 miles of Philadelphia, Pennsylvania, without the consent of the Executive. In addition to any requirements set forth above, in order for any of the above events to constitute "Good Reason", the Executive must (X) inform the Company of the existence of the event within 90 days of the initial existence of the event, after which date the Company shall have no less than 30 days to cure the event which otherwise would constitute "Good Reason" hereunder and (Y) the Executive must terminate employment with the Company for such "Good Reason" no later than two years after the initial existence of the event which prompted the Executive's termination.

(ii) Other than for Good Reason 30 days after notice to the Company.

(c) Termination by the Company. The Company may terminate this Agreement and the Executive's employment by the Company upon notice to the Executive (or personal representative):

(i) at any time and for any reason;

(ii) upon the death of the Executive, in which case this Agreement shall terminate immediately; provided that, such termination shall not prejudice any benefits payable to the Executive's spouse or beneficiaries which are fully vested as of the date of death;

(iii) if the Executive is "permanently disabled" (as defined herein), in which case this Agreement shall terminate immediately; provided that, such termination shall not prejudice any benefits payable to the Executive, the Executive's spouse or beneficiaries which are fully vested as of the date of the termination of this Agreement. For purposes of this Agreement, the Executive shall be considered "**permanently disabled**" when a qualified medical doctor mutually acceptable to the Company and the Executive or the Executive's personal representative shall have certified in writing that: (A) the Executive is unable, because of a medically determinable physical or mental disability, to perform substantially all of the Executive's duties, with or without a reasonable accommodation, for more than 180 calendar days measured from the last full day of work; or (B) by reason of mental or physical disability, it is unlikely that the Executive will be able, within 180 calendar days, to resume substantially all business duties and responsibilities in which the Executive was previously engaged and otherwise discharge the Executive's duties under this Agreement;

(iv) upon the liquidation, dissolution or discontinuance of business by the Company in any manner or the filing of any petition by or against the Company under any federal or state bankruptcy or insolvency laws, which petition shall not be dismissed within 60 days after filing; provided that, such termination shall not prejudice the Executive's rights as a stockholder or a creditor of the Company; or

(v) "for cause" (as defined herein). "**For cause**" shall be determined by the Board by a majority vote without the participation of the Executive in such vote and shall mean:

(A) Any material breach of the terms of this Agreement by the Executive, or the failure of the Executive to diligently and properly perform the Executive's duties for the Company or the Executive's failure to achieve the objectives specified by the Board;

(B) The Executive's misappropriation or unauthorized use of the Company's tangible or intangible property, or breach of the Proprietary Information Agreement (as defined herein) or any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation;

(C) Any material failure to comply with the Company Policies or any other policies and/or directives of the Board;

(D) The Executive's use of illegal drugs or any illegal substance, or the Executive's use of alcohol in any manner that materially interferes with the performance of the Executive's duties under this Agreement;

(E) Any dishonest or illegal action (including, without limitation, embezzlement) or any other action whether or not dishonest or illegal by the Executive which is materially detrimental to the interest and well-being of the Company, including, without limitation, harm to its reputation;

(F) The Executive's failure to fully disclose any material conflict of interest that the Executive may have with the Company in a transaction between the Company and any third party which is materially detrimental to the interest and well-being of the Company; or

(G) Any adverse action or omission by the Executive which would be required to be disclosed pursuant to public securities laws or which would limit the ability of the Company or any entity affiliated with the Company to sell securities under any Federal or state law or which would disqualify the Company or any affiliated entity from any exemption otherwise available to it.

(d) Obligations of the Company Upon Termination.

(i) Upon the termination of this Agreement: (A) by the Executive pursuant to paragraph 5(b)(ii); or (B) by the Company pursuant to paragraph 5(c)(ii), (iii), (iv), or (v), the Company shall have no further obligations hereunder other than the payment of all compensation and other benefits payable to the Executive through the date of such termination which shall be paid on or before the Company's next regularly scheduled payday unless such amount is not then-calculable, in which case payment shall be made on the first regularly scheduled payday after the amount is calculable.

(ii) Upon termination of this Agreement: (A) upon the expiration of the Term, if the Company does not renew the Term for a reason unrelated to Cause; (B) by the Executive pursuant to paragraph 5(b)(i); or (C) by the Company pursuant to paragraph 5(c)(i) and provided that the Executive first executes and does not revoke a release and settlement agreement in the form acceptable to the Company within the time period then-specified by the Company but in any event no later than sixty (60) days after the date of termination (the "**Release**"): (1) the Company shall pay the Executive an amount equal to 12 months of Executive's then-current Base Salary (less all applicable deductions) payable in installments in accordance with the then-current generally applicable payroll schedule of the Company commencing on the first regularly scheduled pay date of the Company processed after Executive has executed, delivered to the Company and not revoked the Release; (2) provided that the Company still offers a health insurance plan, either allow the Executive to continue to participate in the Company's health insurance plan at the level in effect immediately prior to termination (*if permitted under the provisions of such plan*), or provided that the Executive properly elects and maintains continued health insurance coverage under COBRA or its state law equivalent and provided further that such benefits continue to be offered under the Company sponsored plan, the Company shall reimburse the Executive in an amount equal to the cost of the premium for such continued health insurance coverage at the same average level and on the same terms and conditions which applied immediately prior to the date of the Executive's termination for the shorter of (a) 12 months from the date of termination or (b) until the Executive obtains reasonably comparable coverage.

(e) Resignation as Officer and Director. Upon termination of this Agreement and the Executive's employment hereunder for any reason by either party, the Executive shall be deemed to have resigned from all offices and positions the Executive may hold with the Company at such time including without limitation Board membership and/or positions as an officer of the Company.

(f) Payment in Lieu of Notice Period. Upon the termination of this Agreement: (A) pursuant to the expiration of the Term based on a non-renewal notice, if applicable, or (B) by the Executive pursuant to paragraph 5(b)(i) or 5(b)(ii), the Company may, at its sole election, pay the Executive an amount equal to Executive's then-current Base Salary for all or any portion of the applicable notice period required by paragraph 3(b) or paragraph 5(b)(i) or 5(b)(ii) in lieu of all or any portion of such notice period; provided, however, any such election by the Company shall not be deemed to be a termination by the Company that invokes the obligations set forth in Section 5(d)(ii) of this Agreement. Notwithstanding the above, if the Executive requests that Executive's final day of employment occur prior to the expiration of any applicable notice period and the Company consents, pay in lieu of notice shall not be required.

6. Proprietary Information Agreement. The terms of the Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement by and between the Company and the Executive, entered into simultaneously herewith (the "**Proprietary Information Agreement**") and any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation between the Company and the Executive, are hereby incorporated by reference and are a material part of this Agreement.

7. Representations and Warranties.

(a) The Executive represents and warrants to the Company that the Executive's performance of this Agreement and as an employee of the Company does not and will not breach any noncompetition agreement or any agreement to keep in confidence proprietary information acquired by the Executive in confidence or in trust prior to the Executive's employment by the Company. The Executive represents and warrants to the Company that the Executive has not entered into, and agrees not to enter into, any agreement that conflicts with or violates this Agreement.

(b) The Executive represents and warrants to the Company that the Executive has not brought and shall not bring with the Executive to the Company, or use in the performance of the Executive's responsibilities for the Company, any materials or documents of a former employer which are not generally available to the public or which did not belong to the Executive prior to the Executive's employment with the Company, unless the Executive has obtained written authorization from the former employer or other owner for their possession and use and provided the Company with a copy thereof.

8. Indemnification.

(a) By the Employee. The Executive shall indemnify and hold harmless the Company, its directors, officers, stockholders, agents, and employees against all claims, costs, expenses, liabilities, and lost profits, including amounts paid in settlement, incurred by any of them as a result of the breach by the Executive of any provision of Section 2, 6 and/or 7 of this Agreement.

(b) By the Company. The Company will indemnify and hold harmless the Executive from any labilities and expenses arriving from his actions as an officer, director or employee of the Company to the fullest extent permitted by law, excepting any unauthorized acts, intentional or illegal conduct with breaches the terms of this or any other agreement or Company policy, including but not limited to the Proprietary Information Agreement.

9. Notices. All notices, requests, consents, approvals, and other communications to, upon, and between the parties shall be in writing and shall be deemed to have been given, delivered, made, and received when: (a) personally delivered; (b) deposited for next day delivery by Federal Express, or other similar overnight courier services; (c) transmitted via telefacsimile or other similar device to the attention of the Company President with receipt acknowledged; or (d) three days after being sent or mailed by certified mail, postage prepaid and return receipt requested, addressed to the Company at 8601 Six Forks Road, Suite 400, Raleigh, NC 27615, and to the Executive at the address set forth by the signature page below.

10. Effect. This Agreement shall be binding on and inure to the respective benefit of the Company and its successors and assigns and the Executive and his personal representatives.

11. Entire Agreement. This Agreement and the Proprietary Information Agreement and any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation constitute the entire agreement between the parties with respect to the matters set forth herein and supersede all prior agreements and understandings between the parties with respect to the same.

12. Severability. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision.

13. Amendment and Waiver. No provision of this Agreement, including the provisions of this Section, may be amended, modified, deleted, or waived in any manner except by a written agreement executed by the parties.

14. Section 409A Matters. This Agreement is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended and the Treasury Regulations and other applicable guidance thereunder ("**Section 409A**"). To the extent that there is any ambiguity as to whether this Agreement (or any of its provisions) contravenes one or more requirements of Section 409A, such provision shall be interpreted and applied in a matter that does not result in a Section 409A violation. Without limiting the generality of the above:

(a) For clarity, the severance benefits specified in this Agreement (the "**Severance Benefits**") are only payable upon a "separation from service" as defined in Section 409A. The Severance Benefits shall be deemed to be series of separate payments, with each installment being treated as a separate payment. The time and form of payment of any compensation may not be deferred or accelerated to the extent it would result in an impermissible acceleration or deferral under Section 409A.

(b) To the extent this Agreement contains payments which are subject to Section 409A (as opposed to exempt from Section 409A), the Executive's rights to such payments are not subject to anticipation, alienation, sale, transfer, pledge, encumbrance, attachment or garnishment and, where applicable, may only be transferred by will or the laws of descent and distribution.

(c) To the extent the Severance Benefits are intended to be exempt from Section 409A as a result of an "involuntary separation from service" under Section 409A, if all conditions necessary to establish the Executive's entitlement to such Severance Benefits have been satisfied, all Severance Benefits shall be paid or provided in full no later than December 31st of the second calendar year following the calendar year in which the Executive's employment terminated unless another time period is applicable.

(d) If the Employee is a "specified employee" (as defined in Section 409A) on the termination date and a delayed payment is required by Section 409A to avoid a prohibited distribution under Section 409A, then no Severance Benefits that constitute "non-qualified deferred compensation" under Section 409A shall be paid until the earlier of (i) the first day of the 7th month following the date of Employee's "separation from service" as defined in Section 409A, or (ii) the date of Employee's death. Upon the expiration of the applicable deferral period, all payments deferred under this clause shall be paid in a lump sum and any remaining severance benefits shall be paid per the schedule specified in this Agreement.

(e) The Company makes no representation that this Agreement will be exempt from or compliant with Section 409A and makes no affirmative undertaking to preclude Section 409A from applying, but does reserve the right to unilaterally amend this Agreement as may be necessary or advisable to permit the Agreement to be in documentary and operational compliance with Section 409A which determination will be made in the sole discretion of the Company.

15. Governing Law. This Agreement will be governed by and construed according to the laws of the State of North Carolina without regard to conflict of law principles.

16. Consent to Jurisdiction and Venue. Each of the parties agrees that any suit, action, or proceeding arising out of this Agreement may be instituted against it in the state or federal courts located in Wake County, North Carolina. Each of the parties hereby waives any objection that it may have to the venue of any such suit, action, or proceeding, and each of the parties hereby irrevocably consents to the personal jurisdiction of any such court in any such suit, action, or proceeding.

17. Counterparts. This Agreement may be executed in more than one counterpart, each of which shall be deemed an original, and all of which shall be deemed a single agreement.

18. Headings. The headings herein are for convenience only and shall not affect the interpretation of this Agreement.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Jay P. Madan
Jay P. Madan, President

EXECUTIVE:

/s/ Christopher P. Prior, Ph.D.
Christopher P. Prior, Ph.D.

Address:

EXHIBIT A

2016 Milestones for Equity Grant

The following pertains to the Equity Grant set forth in Section 4(a) of the Executive Employment Agreement:

FIRST AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

THIS FIRST AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT (the "**Amendment"**) is entered into as of March 15, 2016 (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Christopher P. Prior (the "**Executive**;" and, together with the Company, the "**Parties**"), who agree to be bound by all of the terms and conditions hereof.

WITNESSETH:

WHEREAS, the Executive and the Company entered into an Executive Employment Agreement on or about October 28, 2015 (the "**Employment Agreement**"), setting forth the terms and conditions of Executive's employment as the Chief Executive Officer of the Company;

WHEREAS, the Executive and the Company desire to amend the Employment Agreement at this time as set forth in this Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Executive and the Company hereby amend the Employment Agreement as follows, effective as of the date hereof:

1. Section 4(a) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"(a) Base Salary. Upon the occurrence of the Minimum Financial Milestone Event (as defined below), the Executive shall be paid an annual salary in the amount of $240,000, which shall be payable in accordance with the then-current payroll schedule of the Company (the "**Base Salary**"), less all applicable taxes and withholdings; *provided*, however, that the Executive shall be paid minimum wage in accordance with applicable state law until such time as the Minimum Financial Milestone Event has occurred. From and after the date of the Minimum Financial Milestone Event, the Executive shall be entitled to payment of the Base Salary in accordance with the then-current payroll schedule of the Company. Upon the occurrence of the Second Financial Milestone Event (as defined below), the Executive's Base Salary shall be increased to $260,000 which shall be paid in accordance with the then-current payroll schedule of the Company commencing on the first regularly scheduled payroll date of the Company after the Second Minimum Financial Milestone Event has occurred. Upon the occurrence of the Third Financial Milestone Event (as defined below), the Executive's Base Salary shall be increased to $300,000, which shall be paid in accordance with the then-current payroll schedule of the Company commencing on the first regularly scheduled payroll date of the Company after the Second Minimum Financial Milestone Event has occurred. The Executive's salary may be increased from time to time by the Board. Notwithstanding anything to the contrary, the Base Salary may be reduced if the Board approves and implements an equal percentage reduction in the base salaries of all of the Company's executive officers, but in no event will such reduction be greater than 15% of the Base Salary. A reduction in the Executive's Base Salary in accordance with the immediately preceding sentence shall not constitute a substantial reduction in salary as described at paragraph 5(b)(i)(A) of this Agreement.

For the purposes of this Agreement, the "**Minimum Financial Milestone Event**" shall mean the sale by the Company of its Equity Securities in a bona fide equity financing following the Effective Date in which the Company receives gross proceeds of not less than $5,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. "**Equity Securities**" means the Company's common stock or preferred stock issued to one or more third parties for bona fide equity financing purposes. The "**Second Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $10,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The "**Third Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event and the Second Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $30,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. For purposes of clarity, the amount of the Minimum Financial Milestone Event shall be included in calculating the Second Milestone Event and the amount of the Minimum Financial Milestone Event and the Second Financial Milestone Event shall be included in calculating the Third Financial Milestone Event."

2. Section 4(b) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"(b) Bonuses.

(i) Upon the occurrence of the Minimum Financial Milestone Event (as defined above) provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $60,000, less applicable withholdings, which shall be paid within 30 days of the occurrence of the Minimum Financial Milestone Event.

(ii) Upon the occurrence of the Second Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $90,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Second Financial Milestone Event. In the event a Second Financial Event is the initial fundraising, the Executive shall be entitled to payment of both bonuses specified under subpart (i) above, and both bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Second Financial Milestone Event.

(iii) Upon the occurrence of the Third Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $175,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Third Financial Milestone Event. In the event the Third Financial Milestone Event is the initial fundraising, the Executive shall be entitled to a payment of each bonus specified under subpart (i) and (ii) above this subpart (iii), and all such bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Third Financial Milestone Event.

For the purposes of subparts (i), (ii) and (iii) above, the Executive shall only be paid the bonuses specified therein if: (A) the Executive is employed by the Company on the effective date of the occurrence of the Minimum Financial Milestone Event the Second Financial Milestone Event, and/or the Third Financial Milestone Event, as appropriate, or has been terminated without Cause prior to such date. For purposes of clarity, if the Executive is not employed by the Company upon the applicable milestone or has been terminated for Cause (as defined herein) prior to the occurrence of the applicable milestone event, the Executive shall have no right to the payment of the bonus specified under subparts (i), (ii) or (iii) hereof."

3. This Amendment is hereby incorporated into and forms a part of the Employment Agreement.

4. Except as modified herein, all other terms and conditions of the Employment Agreement shall continue in full force and effect.

5. This Amendment shall be binding upon the Parties hereto and upon their respective heirs, legal representatives, successors and permitted assigns and shall be governed by and construed in accordance with the laws of the State of North Carolina.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Jay P. Madan, President
Jay P. Madan, President

EXECUTIVE:

By: /s/ Christopher P. Prior
Christopher P. Prior

Address:

SECOND AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

THIS SECOND AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT (the "**Second Amendment"**) is entered into as of March 1, 2017, with an effective date of July 1, 2016 (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Christopher P. Prior (the "**Executive**;" and, together with the Company, the "**Parties**"), who agree to be bound by all of the terms and conditions hereof.

WITNESSETH:

WHEREAS, the Executive and the Company entered into an Executive Employment Agreement on or about October 28, 2015 (the "**Employment Agreement**"), setting forth the terms and conditions of Executive's employment as the Chief Executive Officer of the Company;

WHEREAS, the Executive and the Company entered into a First Amendment to Executive Employment Agreement on or about March 15, 2016 (the "**First Amendment**"); and

WHEREAS, the Executive and the Company desire to amend the Employment Agreement, as amended by the First Amendment, as set forth in this Second Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Executive and the Company hereby amend the Employment Agreement as follows, effective as of the Effective Date set forth above:

1. Section 4(a) of the Employment Agreement entitled "Base Salary" is hereby amended to add the following paragraphs at the end of Section 4(a) relative to Executive's Base Salary:

"Commencing on July 1, 2016, Executive's Base Salary shall be increased so that Executive is paid **$36,000 per year** ($3,000 per month) (to clarify which will be $ 18,000 for period of July 1, 2016 to Dec 31, 2016) (the "**Salary Increase"**), less all applicable taxes and withholdings. Payment of the Salary Increase shall continue until such time as the Minimum Financial Milestone Event has occurred.

Additionally, in the months of July, August and September 2016, the Executive shall be paid a discretionary monthly bonus in addition to the Salary Increase in the amount of $700 per month (to clarify, that the total 2016 Discretionary Bonus would be $ 2,100) (the "**2016 Discretionary Bonus**"). The 2016 Discretionary Bonus shall be paid to the Executive on a monthly basis in each of the months of July, August and September 2016 in accordance with the Company's standard payroll procedure and shall be less all applicable taxes and withholdings. There shall be no further payment of the 2016 Discretionary Bonus from and after September 30, 2016."

2. This Second Amendment is hereby incorporated into and forms a part of the Employment Agreement.

3. Except as modified herein, all other terms and conditions of the Employment Agreement as amended by the First Amendment, shall continue in full force and effect.

4. This Second Amendment shall be binding upon the Parties hereto and upon their respective heirs, legal representatives, successors and permitted assigns and shall be governed by and construed in accordance with the laws of the State of North Carolina.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Second Amendment as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Jay P. Madan
Jay P. Madan, President

EXECUTIVE:

By: /s/ Christopher P. Prior, Ph.D.
Christopher P. Prior, Ph.D.

Address:

THIRD AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

THIS THIRD AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT (the "**Third Amendment"**) is entered into as of March 1, 2017 (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Christopher P. Prior (the "**Executive**;" and, together with the Company, the "**Parties**"), who agree to be bound by all of the terms and conditions hereof.

WITNESSETH:

WHEREAS, the Executive and the Company entered into an Executive Employment Agreement on or about October 28, 2015 (the "**Employment Agreement**"), setting forth the terms and conditions of Executive's employment as the Chief Executive Officer of the Company;

WHEREAS, the Executive and the Company entered into a First Amendment to Executive Employment Agreement on or about March 15, 2016 (the "**First Amendment**");

WHEREAS, the Executive and the Company entered into a Second Amendment to Executive Employment Agreement simultaneously herewith with an effective date of July 1, 2016 (the "**Second Amendment**"); and

WHEREAS, the Executive and the Company desire to amend the Employment Agreement, as amended by the First Amendment and Second Amendment, as set forth in this Third Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Executive and the Company hereby amend the Employment Agreement as follows, effective as of the Effective Date set forth above:

1. Section 4(a) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"(a) Base Salary. Upon the occurrence of the Minimum Financial Milestone Event (as defined below), the Executive shall be paid an annual salary in the amount of $240,000, which shall be payable in accordance with the then-current payroll schedule of the Company (the "**Base Salary**"), less all applicable taxes and withholdings; *provided*, however, that the Executive shall be paid minimum wage in accordance with applicable state law until such time as the Minimum Financial Milestone Event has occurred. From and after the date of the Minimum Financial Milestone Event, the Executive shall be entitled to payment of the Base Salary in accordance with the then-current payroll schedule of the Company. Upon the occurrence of the Second Financial Milestone Event (as defined below), the Executive's Base Salary shall be increased to $260,000 which shall be paid in accordance with the then-current payroll schedule of the Company commencing on the first regularly scheduled payroll date of the Company after the Second Minimum Financial Milestone Event has occurred. Upon the occurrence of the Third Financial Milestone Event (as defined below), the Executive's Base Salary shall be increased to $300,000, which shall be paid in accordance with the then-current payroll schedule of the Company commencing on the first regularly scheduled payroll date of the Company after the Third Minimum Financial Milestone Event has occurred. *Upon the occurrence of the Fourth Financial Milestone Event (as defined below), the Executive's Base Salary shall be increased to $425,000, which shall be paid in accordance with the then-current payroll schedule of the Company commencing on the first regularly scheduled payroll date of the Company after the Fourth Minimum Financial Milestone Event has occurred.* The Executive's salary may be increased from time to time by the Board. Notwithstanding anything to the contrary, the Base Salary may be reduced if the Board approves and implements an equal percentage reduction in the base salaries of all of the Company's executive officers, but in no event will such reduction be greater than 15% of the Base Salary. A reduction in the Executive's Base Salary in accordance with the immediately preceding sentence shall not constitute a substantial reduction in salary as described at paragraph 5(b)(i)(A) of this Agreement.

For the purposes of this Agreement, the "**Minimum Financial Milestone Event**" shall mean the sale by the Company of its Equity Securities in a bona fide equity financing following the Effective Date in which the Company receives gross proceeds of not less than $5,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. "**Equity Securities**" means the Company's common stock or preferred stock issued to one or more third parties for bona fide equity financing purposes. The "**Second Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $10,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The "**Third Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event and the Second Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $30,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. *The "**Fourth Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event, the Second Financial Milestone Event and the Third Financial Milestone Event, as applicable) in which the Company receives aggregate gross proceeds of at least $45,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable*. For purposes of clarity, the amount of the Minimum Financial Milestone Event shall be included in calculating the Second Milestone Event; the amount of the Minimum Financial Milestone Event and the Second Financial Milestone Event shall be included in calculating the Third Financial Milestone Event; *and the amount of the Minimum Financial Milestone Event, the Second Financial Milestone Event and the Third Financial Milestone shall be included in calculating the Fourth Financial Milestone Event*."

2. Section 4(b) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"(b) Bonuses.

(i) Upon the occurrence of the Minimum Financial Milestone Event (as defined above) provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $60,000, less applicable withholdings, which shall be paid within 30 days of the occurrence of the Minimum Financial Milestone Event.

(ii) Upon the occurrence of the Second Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $125,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Second Financial Milestone Event. In the event a Second Financial Event is the initial fundraising, the Executive shall be entitled to payment of both bonuses specified under subpart (i) above, and both bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Second Financial Milestone Event.

(iii) Upon the occurrence of the Third Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $175,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Third Financial Milestone Event. In the event the Third Financial Milestone Event is the initial fundraising, the Executive shall be entitled to a payment of each bonus specified under subpart (i) and (ii) above this subpart (iii), and all such bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Third Financial Milestone Event.

(iv) *Upon the occurrence of the Fourth Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $175,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Forth Financial Milestone Event. In the event the Fourth Financial Milestone Event is the initial fundraising, the Executive shall be entitled to a payment of each bonus specified under subparts (i), (ii) and (iii) above, and all such bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Fourth Financial Milestone Event.*

For the purposes of the bonuses specified under subparts (i) – (iv) above, the Executive shall only be entitled to the bonuses specified therein if the Executive is employed by the Company on the effective date of the occurrence of the Minimum Financial Milestone Event the Second Financial Milestone Event, the Third Financial Milestone Event and/or the Fourth Financial Milestone Event, as appropriate. For purposes of clarity, unless the Executive is employed by the Company on the date of such milestone event, the Executive shall have no right to the payment of the bonus specified under subparts (i), (ii), (iii) or (iv) hereof."

3. This Third Amendment is hereby incorporated into and forms a part of the Employment Agreement.

4. Except as modified herein, all other terms and conditions of the Employment Agreement shall continue in full force and effect.

5. This Third Amendment shall be binding upon the Parties hereto and upon their respective heirs, legal representatives, successors and permitted assigns and shall be governed by and construed in accordance with the laws of the State of North Carolina.

[The remainder of this page is intentionally left blank]

IN WITNESS WHEREOF, the parties have executed this Third Amendment as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Jay P. Madan
Jay P. Madan, President

EXECUTIVE:

By: /s/ Christopher P. Prior, Ph.D.
Christopher P. Prior, Ph.D.

Address:

FOURTH AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

THIS FOURTH AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT (the "**Fourth Amendment"**) is entered into as of August 31, 2017, with an effective date of July 1, 2016 (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Christopher P. Prior (the "**Executive**;" and, together with the Company, the "**Parties**"), who agree to be bound by all of the terms and conditions hereof.

WITNESSETH:

WHEREAS, the Executive and the Company entered into an Executive Employment Agreement on or about October 28, 2015 (the "**Employment Agreement**"), setting forth the terms and conditions of Executive's employment as the Chief Executive Officer of the Company;

WHEREAS, the Executive and the Company entered into a First Amendment to Executive Employment Agreement on or about March 15, 2016 (the "**First Amendment**");

WHEREAS, the Executive and the Company entered into a Second Amendment to Executive Employment Agreement on or about March 1, 2017 (the "**Second Amendment**");

WHEREAS, the Executive and the Company entered into a Third Amendment to Executive Employment Agreement on or about March 1, 2017 (the "**Third Amendment**"); and

WHEREAS, the Executive and the Company desire to amend the Employment Agreement, as amended, as set forth in this Fourth Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Executive and the Company hereby amend the Employment Agreement as follows, effective as of the Effective Date set forth above:

1. The second paragraph of Section 4(a)(i) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"For the purposes of this Agreement, the "**Minimum Financial Milestone Event**" shall mean the sale by the Company of its Equity Securities in a bona fide equity financing following the Effective Date in which the Company receives gross proceeds of not less than $5,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. "**Equity Securities**" means the Company's common stock or preferred stock, or any other securities convertible into the Company's common stock or preferred stock (e.g., convertible promissory notes), issued to one or more third parties for bona fide equity financing purposes. The "**Second Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $10,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The Second Financial Milestone Event will also include any proceeds received from sale of assets, out-licensing and/or partnering agreements. The "**Third Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event and the Second Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $25,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The Third Financial Milestone Event will also include any proceeds received from sale of assets, out-licensing and/or partnering agreements. The "**Fourth Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event, the Second Financial Milestone Event and the Third Financial Milestone Event, as applicable) in which the Company receives aggregate gross proceeds of at least $45,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The Fourth Financial Milestone Event will also include any proceeds received from sale of assets, out-licensing and/or partnering agreements. For purposes of clarity, the amount of the Minimum Financial Milestone Event shall be included in calculating the Second Financial Milestone Event; the amount of the Minimum Financial Milestone Event and the Second Financial Milestone Event shall be included in calculating the Third Financial Milestone Event; and the amount of the Minimum Financial Milestone Event, the Second Financial Milestone Event and the Third Financial Milestone shall be included in calculating the Fourth Financial Milestone Event."

2. This Fourth Amendment is hereby incorporated into and forms a part of the Employment Agreement.

3. Except as modified herein, all other terms and conditions of the Employment Agreement, as amended, shall continue in full force and effect.

4. This Fourth Amendment shall be binding upon the Parties hereto and upon their respective heirs, legal representatives, successors and permitted assigns and shall be governed by and construed in accordance with the laws of the State of North Carolina.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Fourth Amendment as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Jay P. Madan
Jay P. Madan, President

EXECUTIVE:

By: /s/ Christopher P. Prior, Ph.D.
Christopher P. Prior, Ph.D.

Address:

EXECUTIVE EMPLOYMENT AGREEMENT

THIS EXECUTIVE EMPLOYMENT AGREEMENT (the "**Agreement**"), is entered into October 28, 2015, (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Sandeep Laumas (the "**Executive**"), an individual, (collectively, the "**Parties**").

WITNESSETH:

WHEREAS, the Company employed the Executive, and the Executive accepted employment with the Company, commencing on January 1, 2015;

WHEREAS, the Parties wish to formally confirm the terms and conditions of Executive's employment with the Company as set forth in this Agreement; and

WHEREAS, this Agreement shall supersede and replace in its entirety any and all previous agreement(s) by and between the Executive and the Company related to the terms and conditions of employment, whether oral or written.

NOW, THEREFORE, in consideration of the foregoing, of the mutual promises set forth herein, and of other good and valuable consideration, including the continued employment of the Executive by the Company and the compensation to be received by the Executive from the Company pursuant to Section 4 hereof, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending legally to be bound, hereby agree as follows:

1. Employment. Commencing on January 1, 2015, the Company employed and hereby continues to employ the Executive, and the Executive hereby accepts such continued employment, as the Executive Chairman of the Board of Directors ("Chairman") of the Company upon the terms and conditions of this Agreement. The Executive shall report to the Board of Directors of the Company (the "**Board**").

2. Duties. The Executive shall faithfully perform all duties of the Company related to the position or positions held by the Executive, including but not limited to all duties set forth in this Agreement and/or in the Bylaws of the Company related to the position or positions held by the Executive and all additional duties that are prescribed from time to time by the Board or other designated officers of the Company. The Executive shall comply with all Company policies, standards, rules and regulations (the "**Company Policies**") and all applicable government laws, rules and regulations that are now or hereafter in effect. The Executive acknowledges receipt of copies of all written Company Policies that are in effect as of the date of this Agreement. The Executive and the Company acknowledge and agree that the Executive may continue to serve on the board of directors, serve in advisory capacities and have involvement with entities other than the Company while providing services hereunder; *provided*, however, that no such activities will be competitive with the Company. The Executive understands and agrees that (i) no such outside activities in which the Executive engages will interfere with his duties and responsibilities for the Company; (ii) the Executive will be fully transparent and disclose in advance and secure the Company's prior written consent before participating in any such activities, and (iii) will not engage in any activities that will create an actual or perceived conflict of interest. Attached hereto as **Exhibit A** is a list of specifically permissible activities and investments in outside entities as of the Effective Date, which shall be amended from time to time as appropriate.

3. Term. Unless earlier terminated as provided herein, the initial term of this Agreement commenced on January 1, 2015, and shall continue for three years from the Minimum Financial Milestone Event (as defined below) (the "**Term**"). Thereafter, this Agreement shall automatically renew on a year-to-year basis on the same terms and conditions set forth herein unless: (a) earlier terminated or amended as provided herein, or (b) either party gives written notice of non-renewal at least 60 days prior to the end of the initial term or any renewal term of this Agreement. The initial term of this Agreement and all renewals thereof are referred to herein as the "**Term**."

4. Compensation. During the Term, as compensation for the services rendered by the Executive under this Agreement, the Executive shall be entitled to receive the following (all payments are subject to applicable withholdings):

(a) Base Salary. The Executive shall be paid Base Salary as set forth below. The Base Salary may be increased from time to time by the Board. Notwithstanding anything to the contrary, the Base Salary may be reduced if the Board approves and implements an equal percentage reduction in the base salaries of all of the Company's executive officers, but in no event will such reduction be greater than 15% of the Base Salary. A reduction in the Executive's Base Salary in accordance with the immediately preceding sentence shall not constitute a substantial reduction in salary as described at paragraph 5(b)(i)(A) of this Agreement.

(i) 2015 Base Salary: Commencing on January 1, 2015, Executive began accruing an annual salary in the amount of $75,000, which, when and if paid in accordance with this Agreement, shall be less all applicable taxes and withholdings (the "**2015 Base Salary**"). Payment of the 2015 Base Salary to the Executive shall continue to be deferred until such time as a Minimum Financial Milestone Event has occurred; *provided*, however (a) Executive must be employed by the Company at the time the Minimum Financial Milestone Event occurs and (b) the Minimum Financial Milestone Event must occur on or before March 15, 2016, for the Executive to be eligible for payment of the 2015 Base Salary. For purposes of clarity, if Executive's employment terminates before a Minimum Financial Milestone Event has occurred, or if the Minimum Financial Milestone Event does not occur on or before March 15, 2016, the Executive understands and agrees that the Executive forfeits the right to the 2015 Base Salary. Provided that the above-stated conditions have been met, the Company shall pay to the Executive the deferred amount (less all applicable taxes and withholdings) on its first regularly scheduled payroll date after the Minimum Financial Milestone Event has occurred, or on March 15, 2016, if earlier. The Executive's 2015 Base Salary shall also be increased (a) to $150,000 upon the occurrence of the Minimum Financial Milestone Event, and (b) to $175,000 upon the occurrence of the Second Milestone Financial Event, if such events occur in 2015, which increase(s) shall be reflected in the Company's first regularly scheduled payroll date after either the Minimum Financial Milestone Event and/or Second Milestone Event has occurred, as applicable.

For the purposes of this Agreement, the "**Minimum Financial Milestone Event**" shall mean the sale by the Company of its Equity Securities in a bona fide equity financing following the Effective Date in which the Company receives gross proceeds of not less than $5,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. "**Equity Securities**" means the Company's common stock or preferred stock issued to one or more third parties for bona fide equity financing purposes. The "**Second Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $30,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. For purposes of clarity, the amount of the Minimum Financial Milestone Event shall be included in calculating the Second Milestone Event.

(ii) 2016 Base Salary. If a Minimum Financial Milestone Event has not occurred on December 31, 2015, commencing on January 1, 2016, Executive will begin accruing an annual salary in the amount of $90,000, which, when and if paid in accordance with this Agreement, shall be less all applicable taxes and withholdings (the "**2016 Base Salary**"). Payment of the 2016 Base Salary to the Executive shall be deferred until such time as a Minimum Financial Milestone Event has occurred; *provided*, however (a) Executive must be employed by the Company at the time the Minimum Financial Milestone Event occurs, and (b) the Minimum Financial Milestone Event must occur on or before March 15, 2017. For purposes of clarity, if Executive's employment terminates before a Minimum Financial Milestone Event has occurred, or if the Minimum Financial Milestone Event does not occur on or before March 15, 2017, Executive understands and agrees that the Executive forfeits the right to the 2016 Base Salary for the time period of January 1, 2016, through December 31, 2016 (or such date as employment terminates, if sooner). Provided that the above-stated conditions have been met, the Company shall pay to the Executive the deferred amount (less all applicable taxes and withholdings) on its first regularly scheduled payroll date after the Minimum Financial Milestone Event has occurred or on March 15, 2017, if earlier. The Executive's 2016 Base Salary shall also be increased (a) to $150,000 upon the occurrence of the Minimum Financial Milestone Event, and (b) to $175,000 upon the occurrence of the Second Milestone Financial Event, if such events occur in 2016, which increase(s) shall be reflected in the Company's first regularly scheduled payroll date after either the Minimum Financial Milestone Event and/or Second Milestone Event has occurred, as applicable.

(b) Bonuses.

(i) Upon the occurrence of the Minimum Financial Milestone Event (as defined above) provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $25,000, less applicable withholdings, which shall be paid within 30 days of the occurrence of the Minimum Financial Milestone Event.

(ii) Upon the occurrence of the Second Minimum Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $150,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Second Minimum Financial Milestone Event. In the event a Second Minimum Financial Event is the initial fundraising, the Executive shall be entitled to payment of both bonuses specified under subparts (i) above this subpart (ii), and both bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Second Minimum Financial Milestone Event.

For the purposes of subparts (i) and (ii) above, the Executive shall only be paid the bonuses specified therein if: (A) the Executive is employed by the Company on the effective date of the occurrence of the Minimum Financial Milestone Event and/or Second Minimum Financial Milestone Event, as appropriate, or has been terminated without Cause prior to such date. For purposes of clarity, if the Executive is not employed by the Company upon the applicable milestone or has been terminated for Cause (as defined herein) prior to the occurrence of the applicable milestone event, the Executive shall have no right to the payment of the bonus specified under subpart (i) or subpart (ii) hereof.

(iii) Beginning in 2016, the Executive shall be eligible to participate in all bonus or similar incentive plans adopted by the Board. The amount awarded, if any, to the Executive under any bonus or incentive plan shall be in the discretion of the Board or any committee administering such plan, based on its assessment of the Executive's and the Company's performance during the relevant period, but it is the expectation of the Company that the Executive shall be eligible to receive an annual bonus of up to thirty percent (30%) of the Executive's then-current annual Base Salary (the "**Bonus"**), less all applicable taxes and withholdings. If a Bonus is awarded, unless otherwise specifically provided by the Board or committee administering such plan, it shall be paid within 30 days of December 31st in the year following the year in which the Bonus was awarded.

(c) Equity. The Executive will continue to be eligible to receive periodic stock or option awards in the discretion of the Company. The terms of any such awards will be governed by the terms of the Company's equity incentive plans and the applicable award agreements.

(d) Benefits. The Executive shall be entitled to receive those benefits provided from time to time to other executive employees of the Company, in accordance with the terms and conditions of the applicable plan documents; provided that the Executive meets the eligibility requirements thereof. All such benefits are subject to amendment or termination from time to time by the Company without the consent of the Executive or any other employee of the Company.

(e) Paid Time Off. The Executive shall be entitled to four (4) weeks of paid time off ("**PTO**") to be taken at such times as may be approved by the Board. PTO earned in one calendar year may not be used in any subsequent calendar year. Upon the termination of the Executive's employment with the Company, no cash shall be paid in lieu of accrued but unused PTO.

(f) Business Expenses. The Company shall pay, or reimburse the Executive for, all reasonable expenses incurred by the Executive directly related to conduct of the business of the Company; provided that, the Executive complies with the Company's policies for the reimbursement or advancement of business expenses that are now or hereafter in effect.

5. Termination. This Agreement and the Executive's employment by the Company shall or may be terminated, as the case may be, as follows:

(a) Termination upon Expiration of the Term. This Agreement and the Executive's employment by the Company shall terminate upon the expiration of the Term if notice of non-renewal is provided in accordance with the terms of Section 3 hereof.

(b) Termination by the Executive. The Executive may terminate this Agreement and his employment by the Company:

(i) for "Good Reason" (as defined herein). For purposes of this Agreement, "**Good Reason**" shall mean, the existence, without the consent of the Executive, of any of the following events: (A) the Executive's duties and responsibilities or salary are substantially reduced or diminished; (B) the Company materially breaches its obligations under this Agreement, including the failure of the Company to pay the Executive any Base Salary that becomes due and payable within 30 days after the Employee has given the Company written notice thereof; or (C) the Executive's place of employment is relocated by more than 50 miles of Raleigh, North Carolina, without the consent of the Executive. In addition to any requirements set forth above, in order for any of the above events to constitute "Good Reason", the Executive must (X) inform the Company of the existence of the event within 90 days of the initial existence of the event, after which date the Company shall have no less than 30 days to cure the event which otherwise would constitute "Good Reason" hereunder and (Y) the Executive must terminate employment with the Company for such "Good Reason" no later than two years after the initial existence of the event which prompted the Executive's termination.

(ii) Other than for Good Reason 30 days after notice to the Company.

(c) Termination by the Company. The Company may terminate this Agreement and the Executive's employment by the Company upon notice to the Executive (or personal representative):

(i) at any time and for any reason;

(ii) upon the death of the Executive, in which case this Agreement shall terminate immediately; provided that, such termination shall not prejudice any benefits payable to the Executive's spouse or beneficiaries which are fully vested as of the date of death;

(iii) if the Executive is "permanently disabled" (as defined herein), in which case this Agreement shall terminate immediately; provided that, such termination shall not prejudice any benefits payable to the Executive, the Executive's spouse or beneficiaries which are fully vested as of the date of the termination of this Agreement. For purposes of this Agreement, the Executive shall be considered "**permanently disabled**" when a qualified medical doctor mutually acceptable to the Company and the Executive or the Executive's personal representative shall have certified in writing that: (A) the Executive is unable, because of a medically determinable physical or mental disability, to perform substantially all of the Executive's duties, with or without a reasonable accommodation, for more than 180 calendar days measured from the last full day of work; or (B) by reason of mental or physical disability, it is unlikely that the Executive will be able, within 180 calendar days, to resume substantially all business duties and responsibilities in which the Executive was previously engaged and otherwise discharge the Executive's duties under this Agreement;

(iv) upon the liquidation, dissolution or discontinuance of business by the Company in any manner or the filing of any petition by or against the Company under any federal or state bankruptcy or insolvency laws, which petition shall not be dismissed within 60 days after filing; provided that, such termination shall not prejudice the Executive's rights as a stockholder or a creditor of the Company; or

(v) "for cause" (as defined herein). "**For cause**" shall be determined by the Board by a majority vote without the participation of the Executive in such vote and shall mean:

(A) Any material breach of the terms of this Agreement by the Executive, or the failure of the Executive to diligently and properly perform the Executive's duties for the Company or the Executive's failure to achieve the objectives specified by the Board;

(B) The Executive's misappropriation or unauthorized use of the Company's tangible or intangible property, or breach of the Proprietary Information Agreement (as defined herein) or any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation;

(C) Any material failure to comply with the Company Policies or any other policies and/or directives of the Board;

(D) The Executive's use of illegal drugs or any illegal substance, or the Executive's use of alcohol in any manner that materially interferes with the performance of the Executive's duties under this Agreement;

(E) Any dishonest or illegal action (including, without limitation, embezzlement) or any other action whether or not dishonest or illegal by the Executive which is materially detrimental to the interest and well-being of the Company, including, without limitation, harm to its reputation;

(F) The Executive's failure to fully disclose any material conflict of interest that the Executive may have with the Company in a transaction between the Company and any third party which is materially detrimental to the interest and well-being of the Company; or

(G) Any adverse action or omission by the Executive which would be required to be disclosed pursuant to public securities laws or which would limit the ability of the Company or any entity affiliated with the Company to sell securities under any Federal or state law or which would disqualify the Company or any affiliated entity from any exemption otherwise available to it.

(d) Obligations of the Company Upon Termination.

(i) Upon the termination of this Agreement: (A) by the Executive pursuant to paragraph 5(b)(ii); or (B) by the Company pursuant to paragraph 5(c)(ii), (iii), (iv), or (v), the Company shall have no further obligations hereunder other than the payment of all compensation and other benefits payable to the Executive through the date of such termination which shall be paid on or before the Company's next regularly scheduled payday unless such amount is not then-calculable, in which case payment shall be made on the first regularly scheduled payday after the amount is calculable.

(ii) Upon the termination of this Agreement: (A) upon the expiration of the Term, if the Company does not renew the Term for a reason unrelated to Cause; (B) by the Executive pursuant to paragraph 5(b)(i); or (C) by the Company pursuant to paragraph 5(c)(i) and provided that the Executive first executes and does not revoke a release and settlement agreement in the form acceptable to the Company within the time period then-specified by the Company but in any event no later than sixty (60) days after the date of termination (the "**Release**"): (1) the Company shall pay the Executive an amount equal to six months of Executive's then-current Base Salary (less all applicable deductions) payable in installments in accordance with the then-current generally applicable payroll schedule of the Company commencing on the first regularly scheduled pay date of the Company processed after Executive has executed, delivered to the Company and not revoked the Release; (2) provided that the Company still offers a health insurance plan, either allow the Executive to continue to participate in the Company's health insurance plan at the level in effect immediately prior to termination (*if permitted under the provisions of such plan*), or provided that the Executive properly elects and maintains continued health insurance coverage under COBRA or its state law equivalent and provided further that such benefits continue to be offered under the Company sponsored plan, the Company shall reimburse the Executive in an amount equal to the cost of the premium for such continued health insurance coverage at the same average level and on the same terms and conditions which applied immediately prior to the date of the Executive's termination for the shorter of (a) six months from the date of termination or (b) until the Executive obtains reasonably comparable coverage.

(e) Resignation as Officer and Director. Upon termination of this Agreement and the Executive's employment hereunder for any reason by either party, the Executive shall be deemed to have resigned from all offices and positions the Executive may hold with the Company at such time including, without limitation Board membership and/or positions as an officer of the Company.

(f) Payment in Lieu of Notice Period. Upon the termination of this Agreement: (A) pursuant to the expiration of the Term based on a non-renewal notice, if applicable, or (B) by the Executive pursuant to paragraph 5(b)(i) or 5(b)(ii), the Company may, at its sole election, pay the Executive an amount equal to Executive's then-current Base Salary for all or any portion of the applicable notice period required by paragraph 3(b) or paragraph 5(b)(i) or 5(b)(ii) in lieu of all or any portion of such notice period; provided, however, any such election by the Company shall not be deemed to be a termination by the Company that invokes the obligations set forth in Section 5(d)(ii) of this Agreement. Notwithstanding the above, if the Executive requests that Executive's final day of employment occur prior to the expiration of any applicable notice period and the Company consents, pay in lieu of notice shall not be required.

6. Proprietary Information Agreement. The terms of the Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement by and between the Company and the Executive, entered into simultaneously herewith (the "**Proprietary Information Agreement**"), attached hereto in the form substantially similar to **Exhibit B**, and any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation between the Company and the Executive, are hereby incorporated by reference and are a material part of this Agreement.

7. Representations and Warranties.

(a) The Executive represents and warrants to the Company that the Executive's performance of this Agreement and as an employee of the Company does not and will not breach any noncompetition agreement or any agreement to keep in confidence proprietary information acquired by the Executive in confidence or in trust prior to the Executive's employment by the Company. The Executive represents and warrants to the Company that the Executive has not entered into, and agrees not to enter into, any agreement that conflicts with or violates this Agreement.

(b) The Executive represents and warrants to the Company that the Executive has not brought and shall not bring with the Executive to the Company, or use in the performance of the Executive's responsibilities for the Company, any materials or documents of a former employer which are not generally available to the public or which did not belong to the Executive prior to the Executive's employment with the Company, unless the Executive has obtained written authorization from the former employer or other owner for their possession and use and provided the Company with a copy thereof.

8. Indemnification.

(a) By the Employee. The Executive shall indemnify and hold harmless the Company, its directors, officers, stockholders, agents, and employees against all claims, costs, expenses, liabilities, and lost profits, including amounts paid in settlement, incurred by any of them as a result of the breach by the Executive of any provision of Section 2, 6 and/or 7 of this Agreement.

(b) By the Company. The Company will indemnify and hold harmless the Executive from any labilities and expenses arriving from his actions as an officer, director or employee of the Company to the fullest extent permitted by law, excepting any unauthorized acts, intentional or illegal conduct with breaches the terms of this or any other agreement or Company policy, including but not limited to the Proprietary Information Agreement.

9. Notices. All notices, requests, consents, approvals, and other communications to, upon, and between the parties shall be in writing and shall be deemed to have been given, delivered, made, and received when: (a) personally delivered; (b) deposited for next day delivery by Federal Express, or other similar overnight courier services; (c) transmitted via telefacsimile or other similar device to the attention of the Company's President with receipt acknowledged; or (d) three days after being sent or mailed by certified mail, postage prepaid and return receipt requested, addressed to the Company at 8601 Six Forks Road, Suite 400, Raleigh, NC 27615, and to the Executive at the address set forth by the signature page below.

10. Effect. This Agreement shall be binding on and inure to the respective benefit of the Company and its successors and assigns and the Executive and his personal representatives.

11. Entire Agreement. This Agreement, the Proprietary Information Agreement and any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation constitute the entire agreement between the parties with respect to the matters set forth herein and supersede all prior agreements and understandings between the parties with respect to the same.

12. Severability. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision.

13. Amendment and Waiver. No provision of this Agreement, including the provisions of this Section, may be amended, modified, deleted, or waived in any manner except by a written agreement executed by the parties.

14. Section 409A Matters. This Agreement is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended and the Treasury Regulations and other applicable guidance thereunder ("**Section 409A**"). To the extent that there is any ambiguity as to whether this Agreement (or any of its provisions) contravenes one or more requirements of Section 409A, such provision shall be interpreted and applied in a matter that does not result in a Section 409A violation. Without limiting the generality of the above:

(a) For clarity, the severance benefits specified in this Agreement (the "**Severance Benefits**") are only payable upon a "separation from service" as defined in Section 409A. The Severance Benefits shall be deemed to be series of separate payments, with each installment being treated as a separate payment. The time and form of payment of any compensation may not be deferred or accelerated to the extent it would result in an impermissible acceleration or deferral under Section 409A.

(b) To the extent this Agreement contains payments which are subject to Section 409A (as opposed to exempt from Section 409A), the Executive's rights to such payments are not subject to anticipation, alienation, sale, transfer, pledge, encumbrance, attachment or garnishment and, where applicable, may only be transferred by will or the laws of descent and distribution.

(c) To the extent the Severance Benefits are intended to be exempt from Section 409A as a result of an "involuntary separation from service" under Section 409A, if all conditions necessary to establish the Executive's entitlement to such Severance Benefits have been satisfied, all Severance Benefits shall be paid or provided in full no later than December 31st of the second calendar year following the calendar year in which the Executive's employment terminated unless another time period is applicable.

(d) If the Employee is a "specified employee" (as defined in Section 409A) on the termination date and a delayed payment is required by Section 409A to avoid a prohibited distribution under Section 409A, then no Severance Benefits that constitute "non-qualified deferred compensation" under Section 409A shall be paid until the earlier of (i) the first day of the 7th month following the date of Employee's "separation from service" as defined in Section 409A, or (ii) the date of Employee's death. Upon the expiration of the applicable deferral period, all payments deferred under this clause shall be paid in a lump sum and any remaining severance benefits shall be paid per the schedule specified in this Agreement.

(e) The Company makes no representation that this Agreement will be exempt from or compliant with Section 409A and makes no affirmative undertaking to preclude Section 409A from applying, but does reserve the right to unilaterally amend this Agreement as may be necessary or advisable to permit the Agreement to be in documentary and operational compliance with Section 409A which determination will be made in the sole discretion of the Company.

15. Governing Law. This Agreement will be governed by and construed according to the laws of the State of North Carolina without regard to conflict of law principles.

16. Consent to Jurisdiction and Venue. Each of the parties agrees that any suit, action, or proceeding arising out of this Agreement may be instituted against it in the state or federal courts located in Wake County, North Carolina. Each of the parties hereby waives any objection that it may have to the venue of any such suit, action, or proceeding, and each of the parties hereby irrevocably consents to the personal jurisdiction of any such court in any such suit, action, or proceeding.

17. Counterparts. This Agreement may be executed in more than one counterpart, each of which shall be deemed an original, and all of which shall be deemed a single agreement.

18. Headings. The headings herein are for convenience only and shall not affect the interpretation of this Agreement.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Jay P. Madan
Jay P. Madan, President

EXECUTIVE:

By: /s/ Sandeep Laumas
Sandeep Laumas

Address:

EXHIBIT A

Specifically Permissible Activities

- Any and all investments prior to signing of this agreement.
- Investment and advisory work for any companies not competing directly with Innovate’s products.

EXHIBIT B

PROPRIETARY INFORMATION, INVENTIONS,
NON-COMPETITION AND NON-SOLICITATION AGREEMENT

This Proprietary Information, Inventions, Non-competition and Non-Solicitation Agreement ("***Agreement***") is made in consideration for continued employment by Innovate Biopharmaceuticals Inc., a Delaware corporation and successor to GI Therapeutics, Inc., a North Carolina corporation (the "***Company***"), and compensation now and hereafter paid to me. I understand and agree as follows:

1. NONDISCLOSURE AND USE. All Proprietary Information (as defined below) is and shall remain the sole and exclusive property of the Company. At all times during my employment and afterwards I will not disclose or use any Proprietary Information, except as required in connection with my work for the Company. I will take reasonable precautions to safeguard the Proprietary Information. I understand that I am also prohibited from accessing the Company's database for any unauthorized, improper or competitive purpose, both while employed and thereafter. The term "***Proprietary Information***" means any information that relates to the Company's actual or anticipated business or research and development, technical data, trade secrets or know-how, including, but not limited to, research, product plans or other information regarding the Company's products or services and markets therefor, customer lists and customers, software, developments, inventions, processes, formulas, technology, designs, drawings, engineering, hardware configuration information, marketing, finance, other business information or other non-public information that a competitor of the Company could use to the competitive disadvantage of the Company. I further understand that Proprietary Information (i) includes the foregoing information disclosed to me in connection my employment with the Company from the date my employment with the Company first commenced, (ii) does not include any of the foregoing items that is or becomes publicly known through no wrongful act or omission of mine or of others who were under confidentiality obligations as to the item or items involved.

I will not disclose or use any information received by the Company from third parties, except as required in connection with my work for the Company. I will not improperly use or disclose any confidential information or trade secrets of any third party or former employer to whom I have an obligation of confidentiality. My performance of all the terms of this Agreement and as an employee of the Company does not breach any agreement by which I am legally bound, and I agree not to become a party to any such agreement.

2. ASSIGNMENT OF INVENTIONS. I agree to assign and hereby assign to the Company upon creation all my right, title and interest in and to any and all inventions, trade secrets, confidential and proprietary information, and work-product I conceive, create or develop (or have previously conceived, created or developed), whether or not eligible for or covered by patent, copyright or trade secret protection (collectively, "***Inventions***") and whether or not such Inventions constitute works for hire or would otherwise belong to the Company by operation of law, which (i) are related to the Company's business or actual or demonstrably anticipated research or development or (ii) were developed during Company time or using Company resources, that become known to, or are made, conceived, reduced to practice or learned by me, either alone or jointly with others, during the period of my employment with the Company ("***Company Inventions***"). All original works of authorship which are made by me (solely or jointly with others) within the scope of my employment and which are protectable by copyright are "works made for hire" pursuant to United States Copyright Act (17 U.S.C. §101). I further waive any moral rights, if any, I may have in any copyrightable subject matter of any Company Inventions. I will keep an adequate and current record of all Proprietary Information and Company Inventions, which records shall be the property of the Company.

I will not incorporate any non-assignable inventions (defined below) or Prior Inventions (defined below) into any work of the Company without the Company's prior written consent, and, if I do, the Company is hereby granted a nonexclusive, royalty-free, irrevocable, perpetual, fully-paid, worldwide license (with rights to sublicense) in and to all present and future rights in the same. I will promptly disclose to the Company all inventions I develop by myself or jointly with others which I believe are "non-assignable inventions" under N.C.G.S. §66-57.1 (inventions that I developed entirely on my own time without using the Company's equipment, supplies, facility or trade secret information and that do not (a) relate to the Company's business or actual or demonstrably anticipated research or development, or (b) result from any work performed by me for the Company). For clarity, work or inventions I made prior to the commencement of my employment with the Company which are owned in whole or in part by me are described on the signature page hereto; or, if left blank, I affirm there are no such "***Prior Inventions***."

During my employment and thereafter, I will assist the Company in every proper way to obtain and enforce its intellectual property rights, it being understood that the Company shall compensate me at a reasonable rate after my termination for the time actually spent by me and for any reasonable expenses actually incurred by me at the Company's request. If the Company is unable for any reason to secure my signature in connection with obtaining or enforcing the Company's intellectual property rights, then I hereby irrevocably appoint the Company and its duly authorized officers and agents as my agent and attorney in fact, to act on my behalf and to execute and file any required documents and to do all other lawfully permitted acts in furtherance thereof as if done by me.

3. **No Conflicts or Solicitation**. To protect the Company's Proprietary Information, during my employment, I will not engage in any other employment or other activity that is related to the business in which the Company is now involved or becomes involved or has plans to become involved, nor will I engage in any other activities that conflict with my obligations to the Company.

In addition, during my employment and for a period of one year following the termination of my employment with the Company for any reason, I will not, either directly or indirectly, solicit, induce, or encourage (or attempt to do so) any of the Company's employees or other service providers to leave their employment/engagement, or hire or take away such employees or other service providers, either for myself or for any other person or entity. This restriction includes all those who were employed by or performed services for the Company at any time during the one year period immediately before the date my employment terminated.

In addition, during my employment and for a period of one year immediately following the termination of my employment with the Company for any reason, I will not, either directly or indirectly: (a) interfere with the Company's relationships with any of its customers, prospective customers, suppliers, contractors, distribution partners, prospective distribution partners, resellers, or any third party regularly dealing with the Company; or (b) solicit, call upon, divert or actively take away, or attempt to solicit, call upon, divert or take away, for purposes of conducting a business substantially similar to or competitive with the Company's business, any of the Company's customers, prospective customers, suppliers, contractors, distribution partners, prospective distribution partners, or other third party regularly dealing with the Company. This restriction includes any customer to which the Company sold any product, or for which the Company performed any service at any time during the one year period immediately before the date my employment terminated, except that the restriction pertaining to the Company's prospective customers only applies if I became familiar with the prospective customer through my employment.

4. **Covenant Not to Compete**. To protect the Company's Proprietary Information, I agree that during my employment and for a period of one year immediately following the termination of my employment with the Company for any reason, I will not compete with the Company in the Territory (defined below), which for clarity means that I will not, either directly or indirectly, in the Territory (i) serve as an advisor, agent, consultant, director, manager, employee, officer, partner, proprietor or otherwise of any Restricted Business (defined below); (ii) have any ownership interest in any Restricted Business (except for passive ownership of one percent or less of any entity whose securities are publicly traded); or (iii) participate in the organization, financing, operation, management or control of any Restricted Business. "***Restricted Business***" means business in competition with the Company's business as conducted by the Company at any time during the course of my employment with the Company, together with any other business with which I am actively involved in assisting the Company with researching, developing or marketing at the time of the termination of my employment. For clarity, the Company's business as of the date I signed this Agreement includes without limitation: any business related to manufacturing, selling and/or distributing pharmaceutical therapies for gastroenterological disorders, and/or conducting research or development with regard thereto. For further clarity, this covenant does not prohibit my employment with competitors of the Company, if the area in which I will be employed/engaged with such competitor is not competitive with the Company and is not related to the scope of my responsibilities for the Company. "***Territory***" means: (i) the entire world; (ii) North America; (iii) the United States of America; (iv) each state in which the Company does business or did business at any time within one year prior to the termination of my employment with the Company; (v) the States of Maryland, Virginia, North Carolina, South Carolina and Georgia; (vi) the State of North Carolina; and (vii) Wake County. I agree that the foregoing Territory is reasonable and reasonably necessary to protect the Proprietary Information. If, however, a court determines that the Territory described above in subparagraph (i) is too restrictive, then the parties agree the Territory shall be reduced to the area specified in each of the following subsections and in the following order until the court determines an acceptable geographic area: subparagraphs (ii), (iii), (iv), (v), (vi) or (vii). If the court determines that all of the areas are too restrictive, then the parties agree that the court may reduce or limit the area to enable the intent of this Section to be enforced in the largest acceptable area.

5. **Reasonable.** The nature of the Company's products and services are such that its natural market is worldwide. The restrictions in Sections 3 and 4 are reasonable and are reasonably necessary for the protection of Proprietary Information and provide a reasonable way of protecting the Company's business value which will be imparted to me. Through my employment I will receive adequate consideration for any loss of opportunity associated with their provisions. The length of time, geographic area and any other restrictions contained in this Agreement are reasonable to protect the legitimate interests of the Company and do not unfairly restrict or penalize me. However, if any restriction set forth in Section 3 or 4 is found by a court to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall extend only over the maximum period of time, range of activities or geographic area as to which such court shall determine it to be enforceable. A breach of any provision(s) of this Agreement tolls the running of the limitation period and the restriction period with respect to such provision(s) during the breach.

6. **Non-Disparagement**. At all times during my employment and afterwards I will not, directly or indirectly, disparage the Company, its officers or directors, its business, services, products or personnel. This provision is not intended to restrict communications or actions legally protected by state or federal law, including the National Labor Relations Act.

7. **Use of Likeness**. I will not, directly or indirectly, endorse, speak on behalf of, or allow my name or likeness to be used to in any way promote any competitive business or competing product during my employment with the Company. During my employment and after my employment with the Company ends, I consent to the Company's use of my image, likeness, voice, and other characteristics in connection with the Company's operation of the Company's business and its promotion and sale of its products and services. I release the Company from any cause of action which I may have or may have arising out of the use, distribution, adaptation, reproduction, broadcast, or exhibition of such characteristics.

8. **Social Media**. The Company owns all Company-related digital and social media accounts (including all passwords, data posts, digital works and goodwill therein) that I may create, manage, contribute to, or administer during my employment with the Company and including all "followers," connections, fans, subscribers, contacts and other relationships created under such accounts. All use of such accounts will be in accordance with all Company policies in effect from time to time. At any time upon request and immediately upon my termination of employment for any reason, I will surrender full control and access to such Company-related accounts to the Company.

9. **Legal And Equitable Remedies**. Because my services are personal and unique and the Company may not have an adequate remedy at law for a breach or threatened breach of this Agreement, the Company may, in addition to other remedies at law or in equity which may be available, enforce this Agreement by injunction, specific performance or other equitable relief, all without bond.

10. **Employment At-Will and Other Matters.** My employment is at-will, meaning that I or the Company can end my employment at any time for any reason. The Company may notify any employer I may have in the future of my rights and obligations under this Agreement. At any time upon request and on termination of my employment, I will return all Company property to the Company immediately. In addition, all Company property and property situated on the Company's premises is subject to inspection by the Company at any time and I understand that I have no expectation of privacy with regard to the same, including without limitation work areas, computer and communications systems, email and internet records handheld devices or other property used to conduct the business of the Company. Nothing in this Agreement is intended to limit my rights to discuss the terms, wages, and working conditions of employment, as protected by applicable law.

11. **General Provisions**. North Carolina law governs this Agreement. I consent to the personal jurisdiction of and venue in the state and federal courts located in North Carolina. If any provision of this Agreement is found invalid or unenforceable, no other provision is affected. This Agreement is binding on my heirs and all legal representatives. This Agreement benefits and may be enforced by the Company and its agents, parents, subsidiaries, affiliates, successors and assigns. The provisions of this Agreement survive the termination of my employment and the assignment of this Agreement by the Company to any assignee or successor. A waiver by the Company of any breach is not a waiver of any prior or subsequent breach, and a waiver of any specific right shall not be construed as a waiver of any other right. For purposes of this Agreement, the term "employee" shall be deemed to include "consultant," "independent contractor" or "director," and the term "employment," or any variation thereof, shall be deemed to include "engagement" or any variation thereof. My obligations under this Agreement shall apply to any time during which I was previously employed, or am in the future employed, by the Company if no other agreement governs during such period. Any subsequent change or changes in my duties, salary or compensation will not affect the validity or scope of this Agreement. This Agreement is effective as of the first day of my employment with the Company. This Agreement is the final, complete and exclusive agreement between me and the Company with respect to the subject matter hereof and supersedes all prior discussions or agreements, written or verbal, between us with respect to the subject matter hereof. Amendments or waivers to this Agreement must be in writing and signed by the party to be charged to be effective.

I have read this Agreement carefully and understand its terms.

Dated: _____

_____
Sandeep Laumas

_____
Address

Accepted and agreed to:

Innovate Biopharmaceuticals Inc.

By: /Jay P. Madan
Signature/Printed Name

Title: President

****

"PRIOR INVENTIONS"

****

If you have Prior Inventions, please list them in the space below. If no Prior Inventions are identified below, you are affirming that you have no Prior Inventions to identify. If you need extra pages, please attach them and indicate below.

Title	Date of Prior Invention	Brief Description

If a prior confidentiality agreement prevents disclosure above, instead provide a cursory name for each prior invention, a listing of the party or parties to whom it belongs and description of the relationship to that party.

Invention	Parties	Relationship

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FIRST AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

THIS FIRST AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT (the "**Amendment"**) is entered into as of March 15, 2016 (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Sandeep Laumas (the "**Executive**;" and, together with the Company, the "**Parties**"), who agree to be bound by all of the terms and conditions hereof.

WITNESSETH:

WHEREAS, the Executive and the Company entered into an Executive Employment Agreement on or about October 28, 2015 (the "**Employment Agreement**"), setting forth the terms and conditions of Executive's employment as the Executive Chairman of the Board of Directors of the Company;

WHEREAS, the Executive and the Company desire to amend the Employment Agreement at this time as set forth in this Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Executive and the Company hereby amend the Employment Agreement as follows, effective as of the date hereof:

1. The second paragraph of Section 4(a)(i) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"For the purposes of this Agreement, the "**Minimum Financial Milestone Event**" shall mean the sale by the Company of its Equity Securities in a bona fide equity financing following the Effective Date in which the Company receives gross proceeds of not less than $5,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. "**Equity Securities**" means the Company's common stock or preferred stock issued to one or more third parties for bona fide equity financing purposes. The "**Second Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $10,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The "**Third Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event and the Second Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $30,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. For purposes of clarity, the amount of the Minimum Financial Milestone Event shall be included in calculating the Second Milestone Event and the amount of the Minimum Financial Milestone Event and the Second Financial Milestone Event shall be included in calculating the Third Financial Milestone Event.

2. Section 4(a)(ii) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"(ii) 2016 Base Salary. If a Minimum Financial Milestone Event has not occurred on December 31, 2015, commencing on January 1, 2016, Executive will begin accruing an annual salary in the amount of $75,000, which, when and if paid in accordance with this Agreement, shall be less all applicable taxes and withholdings (the "**2016 Base Salary**"). Payment of the 2016 Base Salary to the Executive shall be deferred until such time as a Minimum Financial Milestone Event has occurred; *provided*, however (a) Executive must be employed by the Company at the time the Minimum Financial Milestone Event occurs, and (b) the Minimum Financial Milestone Event must occur on or before March 15, 2017. For purposes of clarity, if Executive's employment terminates before a Minimum Financial Milestone Event has occurred, or if the Minimum Financial Milestone Event does not occur on or before March 15, 2017, Executive understands and agrees that the Executive forfeits the right to the 2016 Base Salary for the time period of January 1, 2016, through December 31, 2016 (or such date as employment terminates, if sooner). Provided that the above-stated conditions have been met, the Company shall pay to the Executive the deferred amount (less all applicable taxes and withholdings) on its first regularly scheduled payroll date after the Minimum Financial Milestone Event has occurred or on March 15, 2017, if earlier. The Executive's 2016 Base Salary shall also be increased (a) to $150,000 upon the occurrence of the Minimum Financial Milestone Event, (b) to $160,000 upon the occurrence of the Second Financial Milestone Financial Event, and (c) to $175,000 upon the occurrence of the Third Financial Milestone Event, if such events occur in 2016, which increase(s) shall be reflected in the Company's first regularly scheduled payroll date after either the Minimum Financial Milestone Event, the Second Milestone Event and/or the Third Financial Milestone Event has occurred, as applicable."

3. Section 4(b) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"(b) Bonuses.

(i) Upon the occurrence of the Minimum Financial Milestone Event (as defined above) provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $25,000, less applicable withholdings, which shall be paid within 30 days of the occurrence of the Minimum Financial Milestone Event.

(ii) Upon the occurrence of the Second Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $80,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Second Financial Milestone Event. In the event a Second Financial Event is the initial fundraising, the Executive shall be entitled to payment of both bonuses specified under subpart (i) above, and both bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Second Financial Milestone Event.

(iii) Upon the occurrence of the Third Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $150,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Third Financial Milestone Event. In the event the Third Financial Milestone Event is the initial fundraising, the Executive shall be entitled to a payment of each bonus specified under subpart (i) and (ii) above this subpart (iii), and all such bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Third Financial Milestone Event.

For the purposes of subparts (i), (ii) and (iii) above, the Executive shall only be paid the bonuses specified therein if: (A) the Executive is employed by the Company on the effective date of the occurrence of the Minimum Financial Milestone Event the Second Financial Milestone Event, and/or the Third Financial Milestone Event, as appropriate, or has been terminated without Cause prior to such date. For purposes of clarity, if the Executive is not employed by the Company upon the applicable milestone or has been terminated for Cause (as defined herein) prior to the occurrence of the applicable milestone event, the Executive shall have no right to the payment of the bonus specified under subparts (i), (ii) or (iii) hereof."

4. This Amendment is hereby incorporated into and forms a part of the Employment Agreement.

5. Except as modified herein, all other terms and conditions of the Employment Agreement shall continue in full force and effect.

6. This Amendment shall be binding upon the Parties hereto and upon their respective heirs, legal representatives, successors and permitted assigns and shall be governed by and construed in accordance with the laws of the State of North Carolina.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Jay P. Madan
Jay P. Madan, President

EXECUTIVE:

By: /s/ Sandeep Laumas
Sandeep Laumas

Address:

SECOND AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

THIS SECOND AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT (the "**Second Amendment"**) is entered into as of March 1, 2017, with an effective date of July 1, 2016 (the "**Effective Date**") by and between Innovate Biopharmaceuticals Inc., a Delaware corporation (the "**Company**"), and Sandeep Laumas (the "**Executive**;" and, together with the Company, the "**Parties**"), who agree to be bound by all of the terms and conditions hereof.

WITNESSETH:

WHEREAS, the Executive and the Company entered into an Executive Employment Agreement on or about October 28, 2015 (the "**Employment Agreement**"), setting forth the terms and conditions of Executive's employment as the President of the Company;

WHEREAS, the Executive and the Company entered into a First Amendment to Executive Employment Agreement on or about March 15, 2016 (the "**First Amendmen**t"); and

WHEREAS, the Executive and the Company desire to amend the Employment Agreement, as amended by the First Amendment, as set forth in this Second Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Executive and the Company hereby amend the Employment Agreement as follows, effective as of the Effective Date set forth above:

1. The second paragraph of Section 4(a)(i) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"For the purposes of this Agreement, the "**Minimum Financial Milestone Event**" shall mean the sale by the Company of its Equity Securities in a bona fide equity financing following the Effective Date in which the Company receives gross proceeds of not less than $5,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. "Equity Securities" means the Company's common stock or preferred stock issued to one or more third parties for bona fide equity financing purposes. The "**Second Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $10,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The "**Third Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event and the Second Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $25,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The "**Fourth Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event, the Second Financial Milestone Event and the Third Financial Milestone Event, as applicable) in which the Company receives aggregate gross proceeds of at least $45,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. For purposes of clarity, the amount of the Minimum Financial Milestone Event shall be included in calculating the Second Milestone Event; the amount of the Minimum Financial Milestone Event and the Second Financial Milestone Event shall be included in calculating the Third Financial Milestone Event; and the amount of the Minimum Financial Milestone Event, the Second Financial Milestone Event and the Third Financial Milestone shall be included in calculating the Fourth Financial Milestone Event."

2. Section 4(a)(ii) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"(ii) 2016 Base Salary. If a Minimum Financial Milestone Event has not occurred on December 31, 2015, commencing on January 1, 2016, Executive will begin accruing an annual salary in the amount of $75,000 which, when and if paid in accordance with this Agreement, shall be less all applicable taxes and withholdings (the "**2016 Base Salary**"). Payment of the 2016 Base Salary to the Executive shall be deferred until such time as a Minimum Financial Milestone Event has occurred; provided, however (a) Executive must be employed by the Company at the time the Minimum Financial Milestone Event occurs, and (b) the Minimum Financial Milestone Event must occur on or before March 15, 2017. For purposes of clarity, if Executive's employment terminates before a Minimum Financial Milestone Event has occurred, or if the Minimum Financial Milestone Event does not occur on or before March 15, 2017, Executive understands and agrees that the Executive forfeits the right to the 2016 Base Salary for the time period of January 1, 2016, through December 31, 2016 (or such date as employment terminates, if sooner). Provided that the above-stated conditions have been met, the Company shall pay to the Executive the deferred amount (less all applicable taxes and withholdings) on its first regularly scheduled payroll date after the Minimum Financial Milestone Event has occurred or on March 15, 2017, if earlier."

3. Section 4(a) of the Employment Agreement is hereby amended to add the following subsections:

"(iii) 2016 Base Salary Increase. Commencing on July 1, 2016, Executive's annual salary shall be increased by $36,000 per year ($3,000 per month) (the "**Salary Increase**"), less applicable taxes and withholdings, so that Executive's annual salary shall be increased from $75,000 to $111,000 per year from and after such date. The Salary Increase shall be paid to the Executive on a monthly basis in the amount set forth above (*that is*, $3,000 per month) and shall not be subject to any of the deferral provisions set forth herein.

iv) 2017 Base Salary. Commencing on January 1, 2017, the Executive's annual salary shall continue at the then-applicate rate, with a portion of the Executive's base salary in the amount of $75,000 to be subject to deferral with such deferral and salary accrual commencing on January 1, 2017, and continuing until such time as a Minimum Financial Milestone Event has occurred, which, when and if the deferred amount is paid in accordance with the terms and conditions hereof, shall be less all applicable taxes and withholdings (the "**2017 Salary Deferral**"). Payment of the Salary Increase shall continue to be paid to the Executive on a monthly basis and shall not be subject to the deferral provisions set forth herein. Payment of the 2017 Salary Deferral shall be deferred and shall not be paid until such time as a Minimum Financial Milestone Event has occurred; provided, however (a) Executive must be employed by the Company at the time the Minimum Financial Milestone Event occurs, and (b) the Minimum Financial Milestone Event must occur on or before March 15, 2018. For purposes of clarity, if Executive's employment terminates before a Minimum Financial Milestone Event has occurred, or if the Minimum Financial Milestone Event does not occur on or before March 15, 2018, the Executive understands and agrees that the Executive forfeits the right to the 2017 Salary Deferral for the time period of January 1, 2017, through December 31, 2017 (or such date as employment terminates, if sooner). Provided that the above-stated conditions have been met, the Company shall pay to the Executive the 2017 Salary Deferral amount (less all applicable taxes and withholdings) on its first regularly scheduled payroll date after the Minimum Financial Milestone Event has occurred or on March 15, 2018, if earlier. From and after the date the Minimum Financial Milestone Event occurs (a) Executive's annual base salary shall be $150,000 per year and will no longer be subject to deferral; (b) at such time as a Second Financial Milestone Event occurs, Executive's annual base salary shall be increased to $160,000 per year; (c) at such time as a Third Financial Milestone Event occurs, Executive's annual base salary shall be increased to $175,0000 per year; and (d) at such time as a Fourth Financial Milestone Event occurs, Executive's annual salary shall be increased to $300,000 per year, which any such salary increase(s) to be reflected on the Company's first regularly scheduled payroll date after the occurrence of such milestone event."

4. Section 4(b) of the Employment Agreement entitled "Bonuses" is hereby amended and restated in its entirety as follows:

"(b) Bonuses.

(i) Minimum Financial Milestone Event. Upon the occurrence of the Minimum Financial Milestone Event (as defined above) provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $25,000 less applicable withholdings, which shall be paid within 30 days of the occurrence of the Minimum Financial Milestone Event.

(ii) Second Financial Milestone Event. Upon the occurrence of the Second Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $110,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Second Financial Milestone Event. In the event a Second Financial Event is the initial fundraising, the Executive shall be entitled to payment of both bonuses specified under subpart (i) above, and both bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Second Financial Milestone Event.

(iii) Third Financial Milestone Event. Upon the occurrence of the Third Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $175,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Third Financial Milestone Event. In the event the Third Financial Milestone Event is the initial fundraising, the Executive shall be entitled to a payment of each bonus specified under subpart (i) and (ii) above this subpart (iii), and all such bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Third Financial Milestone Event.

(iv) Fourth Financial Milestone Event. Upon the occurrence of the Fourth Financial Milestone Event, Executive shall be paid a one-time lump sum cash bonus in the amount of $175,000, less all applicable taxes and withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Fourth Financial Milestone Event. In the event the Fourth Financial Milestone Event is the initial fundraising, the Executive shall be entitled to a payment of the bonuses specified under subparts (i), (ii) and (iii) above (*that is*, the bonuses applicable to the Minimum Financial Milestone Event, the First Financial Milestone Event, the Second Financial Milestone Event and the Third Financial Milestone Event), and the aggregate total of all such bonuses shall be paid to the Executive within 30 days after the occurrence of the Fourth Financial Milestone Event and in all cases no later than March 15th in the year following the year in which the Fourth Financial Milestone Event Occurs."

(v) Discretionary Bonus Award for 2016. For the months of July, August and September 2016, the Executive shall be paid a discretionary monthly bonus in the amount of $700 per month (the "**2016 Discretionary Bonus**"). The 2016 Discretionary Bonus shall be paid to the Executive on a monthly basis in each of the months of July, August and September 2016 in accordance with the Company's standard payroll procedure. The 2016 Discretionary Bonus shall be less all applicable taxes and withholdings. No 2016 Discretionary Bonus shall be paid to the Executive from and after September 30, 2016.

(vi) Discretionary Bonus Award for 2017. If a Minimum Financial Milestone Event has not occurred by March 15, 2017, Executive shall be eligible for a discretionary bonus of $75,000, less all applicable taxes and withholdings (the "**2017 Discretionary Bonus**"), which shall be awarded in the Company's discretion based upon the achievement of certain corporate objectives on or before December 31, 2017, including, but not limited to the sale by the Company of its Equity Securities in a bona fide equity financing in which the Company receives gross proceeds of not less than $5,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) have become publically traded; *provided*, however, the Executive must be employed by the Company on the effective date of the occurrence of the Minimum Financial Milestone Event to be entitled to payment of the 2017 Discretionary Bonus. Such bonus will be paid within 30 days of the occurrence of the Minimum Financial Milestone Event and in all cases no later than March 15, 2018. For purposes of clarity, no 2017 Discretionary Bonus shall be paid to the Executive if the Minimum Financial Milestone Event occurs after December 31, 2017.

For the purposes of the bonuses specified above, the Executive shall only be entitled to the bonuses specified therein if the Executive is employed by the Company on the effective date of the occurrence of the applicable bonus event, including, but not limited to, the date of the Minimum Financial Milestone Event, the Second Financial Milestone Event, the Third Financial Milestone Event and/or the Fourth Financial Milestone Event, as appropriate. For purposes of clarity, unless the Executive is employed by the Company on the date of such milestone event, the Executive shall have no right to the payment of the bonus specified under subparts (i) – (vi) hereof."

5. This Second Amendment is hereby incorporated into and forms a part of the Employment Agreement.

6. Except as modified herein, all other terms and conditions of the Employment Agreement as amended by the First Amendment, shall continue in full force and effect.

7. This Second Amendment shall be binding upon the Parties hereto and upon their respective heirs, legal representatives, successors and permitted assigns and shall be governed by and construed in accordance with the laws of the State of North Carolina.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Second Amendment as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS INC.

By: /s/ Jay Madan
Jay Madan, President

EXECUTIVE:

By: /s/ Sandeep Laumas
Sandeep Laumas

Address:

THIRD AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

THIS THIRD AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT (the "**Third Amendment"**) is entered into as of August 31, 2017, with an effective date of July 1, 2016 (the "**Effective Date**") by and between Innovate Biopharmaceuticals Inc., a Delaware corporation (the "**Company**"), and Sandeep Laumas (the "**Executive**;" and, together with the Company, the "**Parties**"), who agree to be bound by all of the terms and conditions hereof.

WITNESSETH:

WHEREAS, the Executive and the Company entered into an Executive Employment Agreement on or about October 28, 2015 (the "**Employment Agreement**"), setting forth the terms and conditions of Executive's employment as the Executive Chairman of the Board of Directors of the Company;

WHEREAS, the Executive and the Company entered into a First Amendment to Executive Employment Agreement on or about March 15, 2016 (the "**First Amendmen**t");

WHEREAS, the Executive and the Company entered into a Second Amendment to Executive Employment Agreement on or about March 1, 2017 (the "**Second Amendmen**t"); and

WHEREAS, the Executive and the Company desire to amend the Employment Agreement, as amended, as set forth in this Third Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Executive and the Company hereby amend the Employment Agreement as follows, effective as of the Effective Date set forth above:

1. The second paragraph of Section 4(a)(i) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"For the purposes of this Agreement, the "**Minimum Financial Milestone Event**" shall mean the sale by the Company of its Equity Securities in a bona fide equity financing following the Effective Date in which the Company receives gross proceeds of not less than $5,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. "Equity Securities" means the Company's common stock or preferred stock, or any other securities convertible into the Company's common stock or preferred stock (e.g., convertible promissory notes), issued to one or more third parties for bona fide equity financing purposes. The "**Second Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $10,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The Second Financial Milestone Event will also include any proceeds received from sale of assets, out-licensing and/or partnering agreements. The "**Third Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event and the Second Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $25,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The Third Financial Milestone Event will also include any proceeds received from sale of assets, out-licensing and/or partnering agreements. The "**Fourth Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event, the Second Financial Milestone Event and the Third Financial Milestone Event, as applicable) in which the Company receives aggregate gross proceeds of at least $45,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The Fourth Financial Milestone Event will also include any proceeds received from sale of assets, out-licensing and/or partnering agreements. For purposes of clarity, the amount of the Minimum Financial Milestone Event shall be included in calculating the Second Financial Milestone Event; the amount of the Minimum Financial Milestone Event and the Second Financial Milestone Event shall be included in calculating the Third Financial Milestone Event; and the amount of the Minimum Financial Milestone Event, the Second Financial Milestone Event and the Third Financial Milestone shall be included in calculating the Fourth Financial Milestone Event."

2. This Third Amendment is hereby incorporated into and forms a part of the Employment Agreement.

3. Except as modified herein, all other terms and conditions of the Employment Agreement, as amended, shall continue in full force and effect.

4. This Third Amendment shall be binding upon the Parties hereto and upon their respective heirs, legal representatives, successors and permitted assigns and shall be governed by and construed in accordance with the laws of the State of North Carolina.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Third Amendment as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS INC.

By: /s/ Jay Madan
Jay Madan, President

EXECUTIVE:

By: /s/ Sandeep Laumas
Sandeep Laumas

Address:

EXECUTIVE EMPLOYMENT AGREEMENT

THIS EXECUTIVE EMPLOYMENT AGREEMENT (the "**Agreement**"), is entered into October 28, 2015, (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Jay P. Madan (the "**Executive**"), an individual, (collectively, the "**Parties**").

WITNESSETH:

WHEREAS, the Company employed the Executive, and the Executive accepted employment with the Company, commencing on January 1, 2015;

WHEREAS, the Parties wish to formally confirm the terms and conditions of Executive's employment with the Company as set forth in this Agreement; and

WHEREAS, this Agreement shall supersede and replace in its entirety any and all previous agreement(s) by and between the Executive and the Company related to the terms and conditions of employment, whether oral or written.

NOW, THEREFORE, in consideration of the foregoing, of the mutual promises set forth herein, and of other good and valuable consideration, including the continued employment of the Executive by the Company and the compensation to be received by the Executive from the Company pursuant to Section 4 hereof, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending legally to be bound, hereby agree as follows:

1. Employment. Commencing on January 1, 2015, the Company employed and hereby continues to employ the Executive, and the Executive hereby accepts such continued employment, as the President of the Company upon the terms and conditions of this Agreement. The Executive shall report to the Board of Directors of the Company (the "**Board**").

2. Duties. The Executive shall faithfully perform all duties of the Company related to the position or positions held by the Executive, including but not limited to all duties set forth in this Agreement and/or in the Bylaws of the Company related to the position or positions held by the Executive and all additional duties that are prescribed from time to time by the Board or other designated officers of the Company. The Executive shall comply with all Company policies, standards, rules and regulations (the "**Company Policies**") and all applicable government laws, rules and regulations that are now or hereafter in effect. The Executive acknowledges receipt of copies of all written Company Policies that are in effect as of the date of this Agreement. The Executive and the Company acknowledge and agree that the Executive may continue to serve on the board of directors, serve in advisory capacities and have involvement with entities other than the Company while providing services hereunder; *provided*, however, that no such activities will be competitive with the Company. The Executive understands and agrees that (i) no such outside activities in which the Executive engages will interfere with his duties and responsibilities for the Company; (ii) the Executive will be fully transparent and disclose in advance and secure the Company's prior written consent before participating in any such activities, and (iii) will not engage in any activities that will create an actual or perceived conflict of interest. Attached hereto as **Exhibit A** is a list of specifically permissible activities and investments in outside entities as of the Effective Date, which shall be amended from time to time as appropriate.

3. Term. Unless earlier terminated as provided herein, the initial term of this Agreement commenced on January 1, 2015, and shall continue for three years from the Minimum Financial Milestone Event (as defined below) (the "**Term**"). Thereafter, this Agreement shall automatically renew on a year-to-year basis on the same terms and conditions set forth herein unless: (a) earlier terminated or amended as provided herein, or (b) either party gives written notice of non-renewal at least 60 days prior to the end of the initial term or any renewal term of this Agreement. The initial term of this Agreement and all renewals thereof are referred to herein as the "**Term**."

4. Compensation. During the Term, as compensation for the services rendered by the Executive under this Agreement, the Executive shall be entitled to receive the following (all payments are subject to applicable withholdings):

(a) Base Salary. The Executive shall be paid Base Salary as set forth below. The Base Salary may be increased from time to time by the Board. Notwithstanding anything to the contrary, the Base Salary may be reduced if the Board approves and implements an equal percentage reduction in the base salaries of all of the Company's executive officers, but in no event will such reduction be greater than 15% of the Base Salary. A reduction in the Executive's Base Salary in accordance with the immediately preceding sentence shall not constitute a substantial reduction in salary as described at paragraph 5(b)(i)(A) of this Agreement.

(i) 2015 Base Salary: Commencing on January 1, 2015, Executive began accruing an annual salary in the amount of $90,000, which, when and if paid in accordance with this Agreement, shall be less all applicable taxes and withholdings (the "**2015 Base Salary**"). Payment of the 2015 Base Salary to the Executive shall continue to be deferred until such time as a Minimum Financial Milestone Event has occurred; *provided*, however (a) Executive must be employed by the Company at the time the Minimum Financial Milestone Event occurs and (b) the Minimum Financial Milestone Event must occur on or before March 15, 2016, for the Executive to be eligible for payment of the 2015 Base Salary. For purposes of clarity, if Executive's employment terminates before a Minimum Financial Milestone Event has occurred, or if the Minimum Financial Milestone Event does not occur on or before March 15, 2016, the Executive understands and agrees that the Executive forfeits the right to the 2015 Base Salary. Provided that the above-stated conditions have been met, the Company shall pay to the Executive the deferred amount (less all applicable taxes and withholdings) on its first regularly scheduled payroll date after the Minimum Financial Milestone Event has occurred, or on March 15, 2016, if earlier. The Executive's 2015 Base Salary shall also be increased (a) to $180,000 upon the occurrence of the Minimum Financial Milestone Event, and (b) to $250,000 upon the occurrence of the Second Milestone Financial Event, if such events occur in 2015, which increase(s) shall be reflected in the Company's first regularly scheduled payroll date after either the Minimum Financial Milestone Event and/or Second Milestone Event has occurred, as applicable.

For the purposes of this Agreement, the "**Minimum Financial Milestone Event**" shall mean the sale by the Company of its Equity Securities in a bona fide equity financing following the Effective Date in which the Company receives gross proceeds of not less than $5,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. "**Equity Securities**" means the Company's common stock or preferred stock issued to one or more third parties for bona fide equity financing purposes. The "**Second Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $30,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. For purposes of clarity, the amount of the Minimum Financial Milestone Event shall be included in calculating the Second Milestone Event.

(ii) 2016 Base Salary. If a Minimum Financial Milestone Event has not occurred on December 31, 2015, commencing on January 1, 2016, Executive will begin accruing an annual salary in the amount of $90,000, which, when and if paid in accordance with this Agreement, shall be less all applicable taxes and withholdings (the "**2016 Base Salary**"). Payment of the 2016 Base Salary to the Executive shall be deferred until such time as a Minimum Financial Milestone Event has occurred; *provided*, however (a) Executive must be employed by the Company at the time the Minimum Financial Milestone Event occurs, and (b) the Minimum Financial Milestone Event must occur on or before March 15, 2017. For purposes of clarity, if Executive's employment terminates before a Minimum Financial Milestone Event has occurred, or if the Minimum Financial Milestone Event does not occur on or before March 15, 2017, Executive understands and agrees that the Executive forfeits the right to the 2016 Base Salary for the time period of January 1, 2016, through December 31, 2016 (or such date as employment terminates, if sooner). Provided that the above-stated conditions have been met, the Company shall pay to the Executive the deferred amount (less all applicable taxes and withholdings) on its first regularly scheduled payroll date after the Minimum Financial Milestone Event has occurred or on March 15, 2017, if earlier. The Executive's 2016 Base Salary shall also be increased (a) to $180,000 upon the occurrence of the Minimum Financial Milestone Event, and (b) to $250,000 upon the occurrence of the Second Milestone Financial Event, if such events occur in 2016, which increase(s) shall be reflected in the Company's first regularly scheduled payroll date after either the Minimum Financial Milestone Event and/or Second Milestone Event has occurred, as applicable.

(b) Bonuses.

(i) Upon the occurrence of the Minimum Financial Milestone Event (as defined above) provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $30,000, less applicable withholdings, which shall be paid within 30 days of the occurrence of the Minimum Financial Milestone Event.

(ii) Upon the occurrence of the Second Minimum Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $150,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Second Minimum Financial Milestone Event. In the event a Second Minimum Financial Event is the initial fundraising, the Executive shall be entitled to payment of both bonuses specified under subparts (i) above this subpart (ii), and both bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Second Minimum Financial Milestone Event.

For the purposes of subparts (i) and (ii) above, the Executive shall only be paid the bonuses specified therein if: (A) the Executive is employed by the Company on the effective date of the occurrence of the Minimum Financial Milestone Event and/or Second Minimum Financial Milestone Event, as appropriate, or has been terminated without Cause prior to such date. For purposes of clarity, if the Executive is not employed by the Company upon the applicable milestone or has been terminated for Cause (as defined herein) prior to the occurrence of the applicable milestone event, the Executive shall have no right to the payment of the bonus specified under subpart (i) or subpart (ii) hereof.

(iii) Beginning in 2016, the Executive shall be eligible to participate in all bonus or similar incentive plans adopted by the Board. The amount awarded, if any, to the Executive under any bonus or incentive plan shall be in the discretion of the Board or any committee administering such plan, based on its assessment of the Executive's and the Company's performance during the relevant period, but it is the expectation of the Company that the Executive shall be eligible to receive an annual bonus of up to thirty percent (30%) of the Executive's then-current annual Base Salary (the "**Bonus"**), less all applicable taxes and withholdings. If a Bonus is awarded, unless otherwise specifically provided by the Board or committee administering such plan, it shall be paid within 30 days of December 31st in the year following the year in which the Bonus was awarded.

(c) Equity. The Executive will continue to be eligible to receive periodic stock or option awards in the discretion of the Company. The terms of any such awards will be governed by the terms of the Company's equity incentive plans and the applicable award agreements.

(d) Benefits. The Executive shall be entitled to receive those benefits provided from time to time to other executive employees of the Company, in accordance with the terms and conditions of the applicable plan documents; provided that the Executive meets the eligibility requirements thereof. All such benefits are subject to amendment or termination from time to time by the Company without the consent of the Executive or any other employee of the Company.

(e) Paid Time Off. The Executive shall be entitled to four weeks of paid time off ("**PTO**") to be taken at such times as may be approved by the Board. PTO earned in one calendar year may not be used in any subsequent calendar year. Upon the termination of the Executive's employment with the Company, no cash shall be paid in lieu of accrued but unused PTO.

(f) Business Expenses. The Company shall pay, or reimburse the Executive for, all reasonable expenses incurred by the Executive directly related to conduct of the business of the Company; provided that, the Executive complies with the Company's policies for the reimbursement or advancement of business expenses that are now or hereafter in effect.

5. Termination. This Agreement and the Executive's employment by the Company shall or may be terminated, as the case may be, as follows:

(a) Termination upon Expiration of the Term. This Agreement and the Executive's employment by the Company shall terminate upon the expiration of the Term if notice of non-renewal is provided in accordance with the terms of Section 3 hereof.

(b) Termination by the Executive. The Executive may terminate this Agreement and his employment by the Company:

(i) for "Good Reason" (as defined herein). For purposes of this Agreement, "**Good Reason**" shall mean, the existence, without the consent of the Executive, of any of the following events: (A) the Executive's duties and responsibilities or salary are substantially reduced or diminished; (B) the Company materially breaches its obligations under this Agreement, including the failure of the Company to pay the Executive any Base Salary that becomes due and payable within 30 days after the Employee has given the Company written notice thereof; or (C) the Executive's place of employment is relocated by more than 50 miles of Raleigh, North Carolina, without the consent of the Executive. In addition to any requirements set forth above, in order for any of the above events to constitute "Good Reason", the Executive must (X) inform the Company of the existence of the event within 90 days of the initial existence of the event, after which date the Company shall have no less than 30 days to cure the event which otherwise would constitute "Good Reason" hereunder and (Y) the Executive must terminate employment with the Company for such "Good Reason" no later than two years after the initial existence of the event which prompted the Executive's termination.

(ii) Other than for Good Reason 30 days after notice to the Company.

(c) Termination by the Company. The Company may terminate this Agreement and the Executive's employment by the Company upon notice to the Executive (or personal representative):

(i) at any time and for any reason;

(ii) upon the death of the Executive, in which case this Agreement shall terminate immediately; provided that, such termination shall not prejudice any benefits payable to the Executive's spouse or beneficiaries which are fully vested as of the date of death;

(iii) if the Executive is "permanently disabled" (as defined herein), in which case this Agreement shall terminate immediately; provided that, such termination shall not prejudice any benefits payable to the Executive, the Executive's spouse or beneficiaries which are fully vested as of the date of the termination of this Agreement. For purposes of this Agreement, the Executive shall be considered "**permanently disabled**" when a qualified medical doctor mutually acceptable to the Company and the Executive or the Executive's personal representative shall have certified in writing that: (A) the Executive is unable, because of a medically determinable physical or mental disability, to perform substantially all of the Executive's duties, with or without a reasonable accommodation, for more than 180 calendar days measured from the last full day of work; or (B) by reason of mental or physical disability, it is unlikely that the Executive will be able, within 180 calendar days, to resume substantially all business duties and responsibilities in which the Executive was previously engaged and otherwise discharge the Executive's duties under this Agreement;

(iv) upon the liquidation, dissolution or discontinuance of business by the Company in any manner or the filing of any petition by or against the Company under any federal or state bankruptcy or insolvency laws, which petition shall not be dismissed within 60 days after filing; provided that, such termination shall not prejudice the Executive's rights as a stockholder or a creditor of the Company; or

(v) "for cause" (as defined herein). "**For cause**" shall be determined by the Board by a majority vote without the participation of the Executive in such vote and shall mean:

(A) Any material breach of the terms of this Agreement by the Executive, or the failure of the Executive to diligently and properly perform the Executive's duties for the Company or the Executive's failure to achieve the objectives specified by the Board;

(B) The Executive's misappropriation or unauthorized use of the Company's tangible or intangible property, or breach of the Proprietary Information Agreement (as defined herein) or any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation;

(C) Any material failure to comply with the Company Policies or any other policies and/or directives of the Board;

(D) The Executive's use of illegal drugs or any illegal substance, or the Executive's use of alcohol in any manner that materially interferes with the performance of the Executive's duties under this Agreement;

(E) Any dishonest or illegal action (including, without limitation, embezzlement) or any other action whether or not dishonest or illegal by the Executive which is materially detrimental to the interest and well-being of the Company, including, without limitation, harm to its reputation;

(F) The Executive's failure to fully disclose any material conflict of interest that the Executive may have with the Company in a transaction between the Company and any third party which is materially detrimental to the interest and well-being of the Company; or

(G) Any adverse action or omission by the Executive which would be required to be disclosed pursuant to public securities laws or which would limit the ability of the Company or any entity affiliated with the Company to sell securities under any Federal or state law or which would disqualify the Company or any affiliated entity from any exemption otherwise available to it.

(d) Obligations of the Company Upon Termination.

(i) Upon the termination of this Agreement: (A) by the Executive pursuant to paragraph 5(b)(ii); or (B) by the Company pursuant to paragraph 5(c)(ii), (iii), (iv), or (v), the Company shall have no further obligations hereunder other than the payment of all compensation and other benefits payable to the Executive through the date of such termination which shall be paid on or before the Company's next regularly scheduled payday unless such amount is not then-calculable, in which case payment shall be made on the first regularly scheduled payday after the amount is calculable.

(ii) Upon the termination of this Agreement: (A) upon the expiration of the Term, if the Company does not renew the Term for a reason unrelated to Cause; (B) by the Executive pursuant to paragraph 5(b)(i); or (C) by the Company pursuant to paragraph 5(c)(i) and provided that the Executive first executes and does not revoke a release and settlement agreement in the form acceptable to the Company within the time period then-specified by the Company but in any event no later than sixty (60) days after the date of termination (the "**Release**"): (1) the Company shall pay the Executive an amount equal to six months of Executive's then-current Base Salary (less all applicable deductions) payable in installments in accordance with the then-current generally applicable payroll schedule of the Company commencing on the first regularly scheduled pay date of the Company processed after Executive has executed, delivered to the Company and not revoked the Release; (2) provided that the Company still offers a health insurance plan, either allow the Executive to continue to participate in the Company's health insurance plan at the level in effect immediately prior to termination (*if permitted under the provisions of such plan*), or provided that the Executive properly elects and maintains continued health insurance coverage under COBRA or its state law equivalent and provided further that such benefits continue to be offered under the Company sponsored plan, the Company shall reimburse the Executive in an amount equal to the cost of the premium for such continued health insurance coverage at the same average level and on the same terms and conditions which applied immediately prior to the date of the Executive's termination for the shorter of (a) six months from the date of termination or (b) until the Executive obtains reasonably comparable coverage.

(e) Resignation as Officer and Director. Upon termination of this Agreement and the Executive's employment hereunder for any reason by either party, the Executive shall be deemed to have resigned from all offices and positions the Executive may hold with the Company at such time including, without limitation Board membership and/or positions as an officer of the Company.

(f) Payment in Lieu of Notice Period. Upon the termination of this Agreement: (A) pursuant to the expiration of the Term based on a non-renewal notice, if applicable, or (B) by the Executive pursuant to paragraph 5(b)(i) or 5(b)(ii), the Company may, at its sole election, pay the Executive an amount equal to Executive's then-current Base Salary for all or any portion of the applicable notice period required by paragraph 3(b) or paragraph 5(b)(i) or 5(b)(ii) in lieu of all or any portion of such notice period; provided, however, any such election by the Company shall not be deemed to be a termination by the Company that invokes the obligations set forth in Section 5(d)(ii) of this Agreement. Notwithstanding the above, if the Executive requests that Executive's final day of employment occur prior to the expiration of any applicable notice period and the Company consents, pay in lieu of notice shall not be required.

6. Proprietary Information Agreement. The terms of the Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement by and between the Company and the Executive, entered into simultaneously herewith (the "**Proprietary Information Agreement**"), attached hereto in the form substantially similar to **Exhibit B**, and any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation between the Company and the Executive, are hereby incorporated by reference and are a material part of this Agreement.

7. Representations and Warranties.

(a) The Executive represents and warrants to the Company that the Executive's performance of this Agreement and as an employee of the Company does not and will not breach any noncompetition agreement or any agreement to keep in confidence proprietary information acquired by the Executive in confidence or in trust prior to the Executive's employment by the Company. The Executive represents and warrants to the Company that the Executive has not entered into, and agrees not to enter into, any agreement that conflicts with or violates this Agreement.

(b) The Executive represents and warrants to the Company that the Executive has not brought and shall not bring with the Executive to the Company, or use in the performance of the Executive's responsibilities for the Company, any materials or documents of a former employer which are not generally available to the public or which did not belong to the Executive prior to the Executive's employment with the Company, unless the Executive has obtained written authorization from the former employer or other owner for their possession and use and provided the Company with a copy thereof.

8. Indemnification.

(a) By the Employee. The Executive shall indemnify and hold harmless the Company, its directors, officers, stockholders, agents, and employees against all claims, costs, expenses, liabilities, and lost profits, including amounts paid in settlement, incurred by any of them as a result of the breach by the Executive of any provision of Section 2, 6 and/or 7 of this Agreement.

(b) By the Company. The Company will indemnify and hold harmless the Executive from any labilities and expenses arriving from his actions as an officer, director or employee of the Company to the fullest extent permitted by law, excepting any unauthorized acts, intentional or illegal conduct with breaches the terms of this or any other agreement or Company policy, including but not limited to the Proprietary Information Agreement.

9. Notices. All notices, requests, consents, approvals, and other communications to, upon, and between the parties shall be in writing and shall be deemed to have been given, delivered, made, and received when: (a) personally delivered; (b) deposited for next day delivery by Federal Express, or other similar overnight courier services; (c) transmitted via telefacsimile or other similar device to the attention of the Company's President with receipt acknowledged; or (d) three days after being sent or mailed by certified mail, postage prepaid and return receipt requested, addressed to the Company at 8601 Six Forks Road, Suite 400, Raleigh, NC 27615, and to the Executive at the address set forth by the signature page below.

10. Effect. This Agreement shall be binding on and inure to the respective benefit of the Company and its successors and assigns and the Executive and his personal representatives.

11. Entire Agreement. This Agreement, the Proprietary Information Agreement and any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation constitute the entire agreement between the parties with respect to the matters set forth herein and supersede all prior agreements and understandings between the parties with respect to the same.

12. Severability. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision.

13. Amendment and Waiver. No provision of this Agreement, including the provisions of this Section, may be amended, modified, deleted, or waived in any manner except by a written agreement executed by the parties.

14. Section 409A Matters. This Agreement is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended and the Treasury Regulations and other applicable guidance thereunder ("**Section 409A**"). To the extent that there is any ambiguity as to whether this Agreement (or any of its provisions) contravenes one or more requirements of Section 409A, such provision shall be interpreted and applied in a matter that does not result in a Section 409A violation. Without limiting the generality of the above:

(a) For clarity, the severance benefits specified in this Agreement (the "**Severance Benefits**") are only payable upon a "separation from service" as defined in Section 409A. The Severance Benefits shall be deemed to be series of separate payments, with each installment being treated as a separate payment. The time and form of payment of any compensation may not be deferred or accelerated to the extent it would result in an impermissible acceleration or deferral under Section 409A.

(b) To the extent this Agreement contains payments which are subject to Section 409A (as opposed to exempt from Section 409A), the Executive's rights to such payments are not subject to anticipation, alienation, sale, transfer, pledge, encumbrance, attachment or garnishment and, where applicable, may only be transferred by will or the laws of descent and distribution.

(c) To the extent the Severance Benefits are intended to be exempt from Section 409A as a result of an "involuntary separation from service" under Section 409A, if all conditions necessary to establish the Executive's entitlement to such Severance Benefits have been satisfied, all Severance Benefits shall be paid or provided in full no later than December 31st of the second calendar year following the calendar year in which the Executive's employment terminated unless another time period is applicable.

(d) If the Employee is a "specified employee" (as defined in Section 409A) on the termination date and a delayed payment is required by Section 409A to avoid a prohibited distribution under Section 409A, then no Severance Benefits that constitute "non-qualified deferred compensation" under Section 409A shall be paid until the earlier of (i) the first day of the 7th month following the date of Employee's "separation from service" as defined in Section 409A, or (ii) the date of Employee's death. Upon the expiration of the applicable deferral period, all payments deferred under this clause shall be paid in a lump sum and any remaining severance benefits shall be paid per the schedule specified in this Agreement.

(e) The Company makes no representation that this Agreement will be exempt from or compliant with Section 409A and makes no affirmative undertaking to preclude Section 409A from applying, but does reserve the right to unilaterally amend this Agreement as may be necessary or advisable to permit the Agreement to be in documentary and operational compliance with Section 409A which determination will be made in the sole discretion of the Company.

15. Governing Law. This Agreement will be governed by and construed according to the laws of the State of North Carolina without regard to conflict of law principles.

16. Consent to Jurisdiction and Venue. Each of the parties agrees that any suit, action, or proceeding arising out of this Agreement may be instituted against it in the state or federal courts located in Wake County, North Carolina. Each of the parties hereby waives any objection that it may have to the venue of any such suit, action, or proceeding, and each of the parties hereby irrevocably consents to the personal jurisdiction of any such court in any such suit, action, or proceeding.

17. Counterparts. This Agreement may be executed in more than one counterpart, each of which shall be deemed an original, and all of which shall be deemed a single agreement.

18. Headings. The headings herein are for convenience only and shall not affect the interpretation of this Agreement.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS INC.

By: /s/ Sandeep Laumas
Sandeep Laumas, Executive Chairman

EXECUTIVE:

By: /s/ Jay P. Madan
Jay P. Madan

Address:

EXHIBIT A

Specifically Permissible Activities

- Any and all investments prior to signing of this agreement
- Continued investments in therapeutic and diagnostic companies, excluding those targeting gastro-intestinal diseases

EXHIBIT B

PROPRIETARY INFORMATION, INVENTIONS,
NON-COMPETITION AND NON-SOLICITATION AGREEMENT

This Proprietary Information, Inventions, Non-competition and Non-Solicitation Agreement ("***Agreement***") is made in consideration for continued employment by Innovate Biopharmaceuticals Inc., a Delaware corporation and successor to GI Therapeutics, Inc., a North Carolina corporation (the "***Company***"), and compensation now and hereafter paid to me. I understand and agree as follows:

1. NONDISCLOSURE AND USE. All Proprietary Information (as defined below) is and shall remain the sole and exclusive property of the Company. At all times during my employment and afterwards I will not disclose or use any Proprietary Information, except as required in connection with my work for the Company. I will take reasonable precautions to safeguard the Proprietary Information. I understand that I am also prohibited from accessing the Company's database for any unauthorized, improper or competitive purpose, both while employed and thereafter. The term "***Proprietary Information***" means any information that relates to the Company's actual or anticipated business or research and development, technical data, trade secrets or know-how, including, but not limited to, research, product plans or other information regarding the Company's products or services and markets therefor, customer lists and customers, software, developments, inventions, processes, formulas, technology, designs, drawings, engineering, hardware configuration information, marketing, finance, other business information or other non-public information that a competitor of the Company could use to the competitive disadvantage of the Company. I further understand that Proprietary Information (i) includes the foregoing information disclosed to me in connection my employment with the Company from the date my employment with the Company first commenced, (ii) does not include any of the foregoing items that is or becomes publicly known through no wrongful act or omission of mine or of others who were under confidentiality obligations as to the item or items involved.

I will not disclose or use any information received by the Company from third parties, except as required in connection with my work for the Company. I will not improperly use or disclose any confidential information or trade secrets of any third party or former employer to whom I have an obligation of confidentiality. My performance of all the terms of this Agreement and as an employee of the Company does not breach any agreement by which I am legally bound, and I agree not to become a party to any such agreement.

2. ASSIGNMENT OF INVENTIONS. I agree to assign and hereby assign to the Company upon creation all my right, title and interest in and to any and all inventions, trade secrets, confidential and proprietary information, and work-product I conceive, create or develop (or have previously conceived, created or developed), whether or not eligible for or covered by patent, copyright or trade secret protection (collectively, "***Inventions***") and whether or not such Inventions constitute works for hire or would otherwise belong to the Company by operation of law, which (i) are related to the Company's business or actual or demonstrably anticipated research or development or (ii) were developed during Company time or using Company resources, that become known to, or are made, conceived, reduced to practice or learned by me, either alone or jointly with others, during the period of my employment with the Company ("***Company Inventions***"). All original works of authorship which are made by me (solely or jointly with others) within the scope of my employment and which are protectable by copyright are "works made for hire" pursuant to United States Copyright Act (17 U.S.C. §101). I further waive any moral rights, if any, I may have in any copyrightable subject matter of any Company Inventions. I will keep an adequate and current record of all Proprietary Information and Company Inventions, which records shall be the property of the Company.

I will not incorporate any non-assignable inventions (defined below) or Prior Inventions (defined below) into any work of the Company without the Company's prior written consent, and, if I do, the Company is hereby granted a nonexclusive, royalty-free, irrevocable, perpetual, fully-paid, worldwide license (with rights to sublicense) in and to all present and future rights in the same. I will promptly disclose to the Company all inventions I develop by myself or jointly with others which I believe are "non-assignable inventions" under N.C.G.S. §66-57.1 (inventions that I developed entirely on my own time without using the Company's equipment, supplies, facility or trade secret information and that do not (a) relate to the Company's business or actual or demonstrably anticipated research or development, or (b) result from any work performed by me for the Company). For clarity, work or inventions I made prior to the commencement of my employment with the Company which are owned in whole or in part by me are described on the signature page hereto; or, if left blank, I affirm there are no such "***Prior Inventions***."

During my employment and thereafter, I will assist the Company in every proper way to obtain and enforce its intellectual property rights, it being understood that the Company shall compensate me at a reasonable rate after my termination for the time actually spent by me and for any reasonable expenses actually incurred by me at the Company's request. If the Company is unable for any reason to secure my signature in connection with obtaining or enforcing the Company's intellectual property rights, then I hereby irrevocably appoint the Company and its duly authorized officers and agents as my agent and attorney in fact, to act on my behalf and to execute and file any required documents and to do all other lawfully permitted acts in furtherance thereof as if done by me.

3. **No Conflicts or Solicitation**. To protect the Company's Proprietary Information, during my employment, I will not engage in any other employment or other activity that is related to the business in which the Company is now involved or becomes involved or has plans to become involved, nor will I engage in any other activities that conflict with my obligations to the Company.

In addition, during my employment and for a period of one year following the termination of my employment with the Company for any reason, I will not, either directly or indirectly, solicit, induce, or encourage (or attempt to do so) any of the Company's employees or other service providers to leave their employment/engagement, or hire or take away such employees or other service providers, either for myself or for any other person or entity. This restriction includes all those who were employed by or performed services for the Company at any time during the one year period immediately before the date my employment terminated.

In addition, during my employment and for a period of one year immediately following the termination of my employment with the Company for any reason, I will not, either directly or indirectly: (a) interfere with the Company's relationships with any of its customers, prospective customers, suppliers, contractors, distribution partners, prospective distribution partners, resellers, or any third party regularly dealing with the Company; or (b) solicit, call upon, divert or actively take away, or attempt to solicit, call upon, divert or take away, for purposes of conducting a business substantially similar to or competitive with the Company's business, any of the Company's customers, prospective customers, suppliers, contractors, distribution partners, prospective distribution partners, or other third party regularly dealing with the Company. This restriction includes any customer to which the Company sold any product, or for which the Company performed any service at any time during the one year period immediately before the date my employment terminated, except that the restriction pertaining to the Company's prospective customers only applies if I became familiar with the prospective customer through my employment.

4. **Covenant Not to Compete**. To protect the Company's Proprietary Information, I agree that during my employment and for a period of one year immediately following the termination of my employment with the Company for any reason, I will not compete with the Company in the Territory (defined below), which for clarity means that I will not, either directly or indirectly, in the Territory (i) serve as an advisor, agent, consultant, director, manager, employee, officer, partner, proprietor or otherwise of any Restricted Business (defined below); (ii) have any ownership interest in any Restricted Business (except for passive ownership of one percent or less of any entity whose securities are publicly traded); or (iii) participate in the organization, financing, operation, management or control of any Restricted Business. "***Restricted Business***" means business in competition with the Company's business as conducted by the Company at any time during the course of my employment with the Company, together with any other business with which I am actively involved in assisting the Company with researching, developing or marketing at the time of the termination of my employment. For clarity, the Company's business as of the date I signed this Agreement includes without limitation: any business related to manufacturing, selling and/or distributing pharmaceutical therapies for gastroenterological disorders, and/or conducting research or development with regard thereto. For further clarity, this covenant does not prohibit my employment with competitors of the Company, if the area in which I will be employed/engaged with such competitor is not competitive with the Company and is not related to the scope of my responsibilities for the Company. "***Territory***" means: (i) the entire world; (ii) North America; (iii) the United States of America; (iv) each state in which the Company does business or did business at any time within one year prior to the termination of my employment with the Company; (v) the States of Maryland, Virginia, North Carolina, South Carolina and Georgia; (vi) the State of North Carolina; and (vii) Wake County. I agree that the foregoing Territory is reasonable and reasonably necessary to protect the Proprietary Information. If, however, a court determines that the Territory described above in subparagraph (i) is too restrictive, then the parties agree the Territory shall be reduced to the area specified in each of the following subsections and in the following order until the court determines an acceptable geographic area: subparagraphs (ii), (iii), (iv), (v), (vi) or (vii). If the court determines that all of the areas are too restrictive, then the parties agree that the court may reduce or limit the area to enable the intent of this Section to be enforced in the largest acceptable area.

5. **Reasonable.** The nature of the Company's products and services are such that its natural market is worldwide. The restrictions in Sections 3 and 4 are reasonable and are reasonably necessary for the protection of Proprietary Information and provide a reasonable way of protecting the Company's business value which will be imparted to me. Through my employment I will receive adequate consideration for any loss of opportunity associated with their provisions. The length of time, geographic area and any other restrictions contained in this Agreement are reasonable to protect the legitimate interests of the Company and do not unfairly restrict or penalize me. However, if any restriction set forth in Section 3 or 4 is found by a court to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall extend only over the maximum period of time, range of activities or geographic area as to which such court shall determine it to be enforceable. A breach of any provision(s) of this Agreement tolls the running of the limitation period and the restriction period with respect to such provision(s) during the breach.

6. **Non-Disparagement**. At all times during my employment and afterwards I will not, directly or indirectly, disparage the Company, its officers or directors, its business, services, products or personnel. This provision is not intended to restrict communications or actions legally protected by state or federal law, including the National Labor Relations Act.

7. **Use of Likeness**. I will not, directly or indirectly, endorse, speak on behalf of, or allow my name or likeness to be used to in any way promote any competitive business or competing product during my employment with the Company. During my employment and after my employment with the Company ends, I consent to the Company's use of my image, likeness, voice, and other characteristics in connection with the Company's operation of the Company's business and its promotion and sale of its products and services. I release the Company from any cause of action which I may have or may have arising out of the use, distribution, adaptation, reproduction, broadcast, or exhibition of such characteristics.

8. **Social Media**. The Company owns all Company-related digital and social media accounts (including all passwords, data posts, digital works and goodwill therein) that I may create, manage, contribute to, or administer during my employment with the Company and including all "followers," connections, fans, subscribers, contacts and other relationships created under such accounts. All use of such accounts will be in accordance with all Company policies in effect from time to time. At anytime upon request and immediately upon my termination of employment for any reason, I will surrender full control and access to such Company-related accounts to the Company.

9. **Legal And Equitable Remedies**. Because my services are personal and unique and the Company may not have an adequate remedy at law for a breach or threatened breach of this Agreement, the Company may, in addition to other remedies at law or in equity which may be available, enforce this Agreement by injunction, specific performance or other equitable relief, all without bond.

10. **Employment At-Will and Other Matters.** My employment is at-will, meaning that I or the Company can end my employment at any time for any reason. The Company may notify any employer I may have in the future of my rights and obligations under this Agreement. At any time upon request and on termination of my employment, I will return all Company property to the Company immediately. In addition, all Company property and property situated on the Company's premises is subject to inspection by the Company at any time and I understand that I have no expectation of privacy with regard to the same, including without limitation work areas, computer and communications systems, email and internet records handheld devices or other property used to conduct the business of the Company. Nothing in this Agreement is intended to limit my rights to discuss the terms, wages, and working conditions of employment, as protected by applicable law.

11. **General Provisions**. North Carolina law governs this Agreement. I consent to the personal jurisdiction of and venue in the state and federal courts located in North Carolina. If any provision of this Agreement is found invalid or unenforceable, no other provision is affected. This Agreement is binding on my heirs and all legal representatives. This Agreement benefits and may be enforced by the Company and its agents, parents, subsidiaries, affiliates, successors and assigns. The provisions of this Agreement survive the termination of my employment and the assignment of this Agreement by the Company to any assignee or successor. A waiver by the Company of any breach is not a waiver of any prior or subsequent breach, and a waiver of any specific right shall not be construed as a waiver of any other right. For purposes of this Agreement, the term "employee" shall be deemed to include "consultant," "independent contractor" or "director," and the term "employment," or any variation thereof, shall be deemed to include "engagement" or any variation thereof. My obligations under this Agreement shall apply to any time during which I was previously employed, or am in the future employed, by the Company if no other agreement governs during such period. Any subsequent change or changes in my duties, salary or compensation will not affect the validity or scope of this Agreement. This Agreement is effective as of the first day of my employment with the Company. This Agreement is the final, complete and exclusive agreement between me and the Company with respect to the subject matter hereof and supersedes all prior discussions or agreements, written or verbal, between us with respect to the subject matter hereof. Amendments or waivers to this Agreement must be in writing and signed by the party to be charged to be effective.

I have read this Agreement carefully and understand its terms.

Dated: _____

_____
Jay P. Madan

_____
Address

Accepted and agreed to:

Innovate Biopharmaceuticals Inc.

By: /Sandeep Laumas
Signature/Printed Name

Title: Executive Chairman

****

"PRIOR INVENTIONS"

****

If you have Prior Inventions, please list them in the space below. If no Prior Inventions are identified below, you are affirming that you have no Prior Inventions to identify. If you need extra pages, please attach them and indicate below.

Title	Date of Prior Invention	Brief Description

If a prior confidentiality agreement prevents disclosure above, instead provide a cursory name for each prior invention, a listing of the party or parties to whom it belongs and description of the relationship to that party.

Invention	Parties	Relationship

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FIRST AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

THIS FIRST AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT (the "**Amendment"**) is entered into as of March 15, 2016 (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Jay P. Madan (the "**Executive**;" and, together with the Company, the "**Parties**"), who agree to be bound by all of the terms and conditions hereof.

WITNESSETH:

WHEREAS, the Executive and the Company entered into an Executive Employment Agreement on or about October 28, 2015 (the "**Employment Agreement**"), setting forth the terms and conditions of Executive's employment as the President of the Company;

WHEREAS, the Executive and the Company desire to amend the Employment Agreement at this time as set forth in this Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Executive and the Company hereby amend the Employment Agreement as follows, effective as of the date hereof:

1. The second paragraph of Section 4(a)(i) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"For the purposes of this Agreement, the "**Minimum Financial Milestone Event**" shall mean the sale by the Company of its Equity Securities in a bona fide equity financing following the Effective Date in which the Company receives gross proceeds of not less than $5,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. "**Equity Securities**" means the Company's common stock or preferred stock issued to one or more third parties for bona fide equity financing purposes. The "**Second Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $10,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The "**Third Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event and the Second Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $30,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. For purposes of clarity, the amount of the Minimum Financial Milestone Event shall be included in calculating the Second Milestone Event and the amount of the Minimum Financial Milestone Event and the Second Financial Milestone Event shall be included in calculating the Third Financial Milestone Event.

2. Section 4(a)(ii) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"(ii) 2016 Base Salary. If a Minimum Financial Milestone Event has not occurred on December 31, 2015, commencing on January 1, 2016, Executive will begin accruing an annual salary in the amount of $90,000, which, when and if paid in accordance with this Agreement, shall be less all applicable taxes and withholdings (the "**2016 Base Salary**"). Payment of the 2016 Base Salary to the Executive shall be deferred until such time as a Minimum Financial Milestone Event has occurred; *provided*, however (a) Executive must be employed by the Company at the time the Minimum Financial Milestone Event occurs, and (b) the Minimum Financial Milestone Event must occur on or before March 15, 2017. For purposes of clarity, if Executive's employment terminates before a Minimum Financial Milestone Event has occurred, or if the Minimum Financial Milestone Event does not occur on or before March 15, 2017, Executive understands and agrees that the Executive forfeits the right to the 2016 Base Salary for the time period of January 1, 2016, through December 31, 2016 (or such date as employment terminates, if sooner). Provided that the above-stated conditions have been met, the Company shall pay to the Executive the deferred amount (less all applicable taxes and withholdings) on its first regularly scheduled payroll date after the Minimum Financial Milestone Event has occurred or on March 15, 2017, if earlier. The Executive's 2016 Base Salary shall also be increased (a) to $180,000 upon the occurrence of the Minimum Financial Milestone Event, (b) to $210,000 upon the occurrence of the Second Financial Milestone Financial Event, and (c) to $250,000 upon the occurrence of the Third Financial Milestone Event, if such events occur in 2016, which increase(s) shall be reflected in the Company's first regularly scheduled payroll date after either the Minimum Financial Milestone Event, the Second Milestone Event and/or the Third Financial Milestone Event has occurred, as applicable."

3. Section 4(b) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"(b) Bonuses.

(i) Upon the occurrence of the Minimum Financial Milestone Event (as defined above) provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $30,000, less applicable withholdings, which shall be paid within 30 days of the occurrence of the Minimum Financial Milestone Event.

(ii) Upon the occurrence of the Second Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $100,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Second Financial Milestone Event. In the event a Second Financial Event is the initial fundraising, the Executive shall be entitled to payment of both bonuses specified under subpart (i) above, and both bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Second Financial Milestone Event.

(iii) Upon the occurrence of the Third Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $150,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Third Financial Milestone Event. In the event the Third Financial Milestone Event is the initial fundraising, the Executive shall be entitled to a payment of each bonus specified under subpart (i) and (ii) above this subpart (iii), and all such bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Third Financial Milestone Event.

For the purposes of subparts (i), (ii) and (iii) above, the Executive shall only be paid the bonuses specified therein if: (A) the Executive is employed by the Company on the effective date of the occurrence of the Minimum Financial Milestone Event the Second Financial Milestone Event, and/or the Third Financial Milestone Event, as appropriate, or has been terminated without Cause prior to such date. For purposes of clarity, if the Executive is not employed by the Company upon the applicable milestone or has been terminated for Cause (as defined herein) prior to the occurrence of the applicable milestone event, the Executive shall have no right to the payment of the bonus specified under subparts (i), (ii) or (iii) hereof."

4. This Amendment is hereby incorporated into and forms a part of the Employment Agreement.

5. Except as modified herein, all other terms and conditions of the Employment Agreement shall continue in full force and effect.

6. This Amendment shall be binding upon the Parties hereto and upon their respective heirs, legal representatives, successors and permitted assigns and shall be governed by and construed in accordance with the laws of the State of North Carolina.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Sandeep Laumas
Sandeep Laumas, Executive Chairman

EXECUTIVE:

By: /s/ Jay P. Madan
Jay P. Madan

Address:

SECOND AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

THIS SECOND AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT (the "**Second Amendment"**) is entered into as of March 1, 2017, with an effective date of July 1, 2016 (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Jay P. Madan (the "**Executive**;" and, together with the Company, the "**Parties**"), who agree to be bound by all of the terms and conditions hereof.

WITNESSETH:

WHEREAS, the Executive and the Company entered into an Executive Employment Agreement on or about October 28, 2015 (the "**Employment Agreement**"), setting forth the terms and conditions of Executive's employment as the President of the Company;

WHEREAS, the Executive and the Company entered into a First Amendment to Executive Employment Agreement on or about March 15, 2016 (the "**First Amendmen**t"); and

WHEREAS, the Executive and the Company desire to amend the Employment Agreement, as amended by the First Amendment, as set forth in this Second Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Executive and the Company hereby amend the Employment Agreement as follows, effective as of the Effective Date set forth above:

1. The second paragraph of Section 4(a)(i) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"For the purposes of this Agreement, the "**Minimum Financial Milestone Event**" shall mean the sale by the Company of its Equity Securities in a bona fide equity financing following the Effective Date in which the Company receives gross proceeds of not less than $5,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. "Equity Securities" means the Company's common stock or preferred stock issued to one or more third parties for bona fide equity financing purposes. The "**Second Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $10,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The "**Third Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event and the Second Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $25,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The "**Fourth Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event, the Second Financial Milestone Event and the Third Financial Milestone Event, as applicable) in which the Company receives aggregate gross proceeds of at least $45,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. For purposes of clarity, the amount of the Minimum Financial Milestone Event shall be included in calculating the Second Milestone Event; the amount of the Minimum Financial Milestone Event and the Second Financial Milestone Event shall be included in calculating the Third Financial Milestone Event; and the amount of the Minimum Financial Milestone Event, the Second Financial Milestone Event and the Third Financial Milestone shall be included in calculating the Fourth Financial Milestone Event.

2. Section 4(a)(ii) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"(ii) 2016 Base Salary. If a Minimum Financial Milestone Event has not occurred on December 31, 2015, commencing on January 1, 2016, Executive will begin accruing an annual salary in the amount of $90,000 which, when and if paid in accordance with this Agreement, shall be less all applicable taxes and withholdings (the "**2016 Base Salary**"). Payment of the 2016 Base Salary to the Executive shall be deferred until such time as a Minimum Financial Milestone Event has occurred; provided, however (a) Executive must be employed by the Company at the time the Minimum Financial Milestone Event occurs, and (b) the Minimum Financial Milestone Event must occur on or before March 15, 2017. For purposes of clarity, if Executive's employment terminates before a Minimum Financial Milestone Event has occurred, or if the Minimum Financial Milestone Event does not occur on or before March 15, 2017, Executive understands and agrees that the Executive forfeits the right to the 2016 Base Salary for the time period of January 1, 2016, through December 31, 2016 (or such date as employment terminates, if sooner). Provided that the above-stated conditions have been met, the Company shall pay to the Executive the deferred amount (less all applicable taxes and withholdings) on its first regularly scheduled payroll date after the Minimum Financial Milestone Event has occurred or on March 15, 2017, if earlier.

3. Section 4(a) of the Employment Agreement is hereby amended to add the following subsections:

"(iii) 2016 Base Salary Increase. Commencing on July 1, 2016, Executive's annual salary shall be increased by $60,000 per year ($5,000 per month) (the "**Salary Increase**"), less applicable taxes and withholdings, so that Executive's annual salary shall be increased from $90,000 to $150,000 per year from and after such date. The Salary Increase shall be paid to the Executive on a monthly basis in the amount set forth above (*that is*, $5,000 per month) and shall not be subject to any of the deferral provisions set forth herein.

iv) 2017 Base Salary. Commencing on January 1, 2017, the Executive's annual salary shall continue at the then-applicate rate, with a portion of the Executive's base salary in the amount of $90,000 to be subject to deferral with such deferral and salary accrual commencing on January 1, 2017, and continuing until such time as a Minimum Financial Milestone Event has occurred, which, when and if the deferred amount is paid in accordance with the terms and conditions hereof, shall be less all applicable taxes and withholdings (the "**2017 Salary Deferral**"). Payment of the Salary Increase shall continue to be paid to the Executive on a monthly basis and shall not be subject to the deferral provisions set forth herein. Payment of the 2017 Salary Deferral shall be deferred and shall not be paid until such time as a Minimum Financial Milestone Event has occurred; provided, however (a) Executive must be employed by the Company at the time the Minimum Financial Milestone Event occurs, and (b) the Minimum Financial Milestone Event must occur on or before March 15, 2018. For purposes of clarity, if Executive's employment terminates before a Minimum Financial Milestone Event has occurred, or if the Minimum Financial Milestone Event does not occur on or before March 15, 2018, the Executive understands and agrees that the Executive forfeits the right to the 2017 Salary Deferral for the time period of January 1, 2017, through December 31, 2017 (or such date as employment terminates, if sooner). Provided that the above-stated conditions have been met, the Company shall pay to the Executive the 2017 Salary Deferral amount (less all applicable taxes and withholdings) on its first regularly scheduled payroll date after the Minimum Financial Milestone Event has occurred or on March 15, 2018, if earlier. From and after the date the Minimum Financial Milestone Event occurs (a) Executive's annual base salary shall be $180,000 per year and will no longer be subject to deferral; (b) at such time as a Second Financial Milestone Event occurs, Executive's annual base salary shall be increased to $210,000 per year; (c) at such time as a Third Financial Milestone Event occurs, Executive's annual base salary shall be increased to $250,000 per year; and (d) at such time as a Fourth Financial Milestone Event occurs, Executive's annual salary shall be increased to $350,000 per year, which any such salary increase(s) to be reflected on the Company's first regularly scheduled payroll date after the occurrence of such milestone event."

4. Section 4(b) of the Employment Agreement entitled "Bonuses" is hereby amended and restated in its entirety as follows:

"(b) Bonuses.

(i) Minimum Financial Milestone Event. Upon the occurrence of the Minimum Financial Milestone Event (as defined above) provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $30,000, less applicable withholdings, which shall be paid within 30 days of the occurrence of the Minimum Financial Milestone Event.

(ii) Second Financial Milestone Event. Upon the occurrence of the Second Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $115,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Second Financial Milestone Event. In the event a Second Financial Event is the initial fundraising, the Executive shall be entitled to payment of both bonuses specified under subpart (i) above, and both bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Second Financial Milestone Event.

(iii) Third Financial Milestone Event. Upon the occurrence of the Third Financial Milestone Event, provided that the conditions set forth below have been satisfied, the Executive shall be paid a one-time lump sum cash bonus in the amount of $150,000, less all applicable withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Third Financial Milestone Event. In the event the Third Financial Milestone Event is the initial fundraising, the Executive shall be entitled to a payment of each bonus specified under subpart (i) and (ii) above this subpart (iii), and all such bonuses shall be paid to the Executive, less applicable withholdings, within 30 days of the occurrence of the Third Financial Milestone Event.

(iv) Fourth Financial Milestone Event. Upon the occurrence of the Fourth Financial Milestone Event, Executive shall be paid a one-time lump sum cash bonus in the amount of $125,000, less all applicable taxes and withholdings, which shall be paid to the Executive within 30 days of the occurrence of the Fourth Financial Milestone Event. In the event the Fourth Financial Milestone Event is the initial fundraising, the Executive shall be entitled to a payment of the bonuses specified under subparts (i), (ii) and (iii) above (*that is*, the bonuses applicable to the Minimum Financial Milestone Event, the First Financial Milestone Event, the Second Financial Milestone Event and the Third Financial Milestone Event), and the aggregate total of all such bonuses shall be paid to the Executive within 30 days after the occurrence of the Fourth Financial Milestone Event and in all cases no later than March 15th in the year following the year in which the Fourth Financial Milestone Event Occurs."

(v) Discretionary Bonus Award for 2016. For the months of July, August and September 2016, the Executive shall be paid a discretionary monthly bonus in the amount of $1,500 per month (the "**2016 Discretionary Bonus**"). The 2016 Discretionary Bonus shall be paid to the Executive on a monthly basis in each of the months of July, August and September 2016 in accordance with the Company's standard payroll procedure. The 2016 Discretionary Bonus shall be less all applicable taxes and withholdings. No 2016 Discretionary Bonus shall be paid to the Executive from and after September 30, 2016.

(vi) Discretionary Bonus Award for 2017. If a Minimum Financial Milestone Event has not occurred by March 15, 2017, Executive shall be eligible for a discretionary bonus of $90,000, less all applicable taxes and withholdings (the "**2017 Discretionary Bonus**"), which shall be awarded in the Company's discretion based upon the achievement of certain corporate objectives on or before December 31, 2017, including, but not limited to the sale by the Company of its Equity Securities in a bona fide equity financing in which the Company receives gross proceeds of not less than $5,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) have become publically traded; *provided*, however, the Executive must be employed by the Company on the effective date of the occurrence of the Minimum Financial Milestone Event to be entitled to payment of the 2017 Discretionary Bonus. Such bonus will be paid within 30 days of the occurrence of the Minimum Financial Milestone Event and in all cases no later than March 15, 2018. For purposes of clarity, no 2017 Discretionary Bonus shall be paid to the Executive if the Minimum Financial Milestone Event occurs after December 31, 2017.

For the purposes of the bonuses specified above, the Executive shall only be entitled to the bonuses specified therein if the Executive is employed by the Company on the effective date of the occurrence of the applicable bonus event, including, but not limited to, the date of the Minimum Financial Milestone Event, the Second Financial Milestone Event, the Third Financial Milestone Event and/or the Fourth Financial Milestone Event, as appropriate. For purposes of clarity, unless the Executive is employed by the Company on the date of such milestone event, the Executive shall have no right to the payment of the bonus specified under subparts (i) – (vi) hereof."

5. This Second Amendment is hereby incorporated into and forms a part of the Employment Agreement.

6. Except as modified herein, all other terms and conditions of the Employment Agreement as amended by the First Amendment, shall continue in full force and effect.

7. This Second Amendment shall be binding upon the Parties hereto and upon their respective heirs, legal representatives, successors and permitted assigns and shall be governed by and construed in accordance with the laws of the State of North Carolina.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Second Amendment as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Sandeep Laumas
Sandeep Laumas, Executive Chairman

EXECUTIVE:

By: /s/ Jay P. Madan
Jay P. Madan

Address:

THIRD AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT

THIS THIRD AMENDMENT TO EXECUTIVE EMPLOYMENT AGREEMENT (the "**Third Amendment"**) is entered into as of August 31, 2017, with an effective date of July 1, 2016 (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Jay P. Madan (the "**Executive**;" and, together with the Company, the "**Parties**"), who agree to be bound by all of the terms and conditions hereof.

WITNESSETH:

WHEREAS, the Executive and the Company entered into an Executive Employment Agreement on or about October 28, 2015 (the "**Employment Agreement**"), setting forth the terms and conditions of Executive's employment as the President of the Company;

WHEREAS, the Executive and the Company entered into a First Amendment to Executive Employment Agreement on or about March 15, 2016 (the "**First Amendmen**t");

WHEREAS, the Executive and the Company entered into a Second Amendment to Executive Employment Agreement on or about March 1, 2017 (the "**Second Amendment**"); and

WHEREAS, the Executive and the Company desire to amend the Employment Agreement, as amended, as set forth in this Third Amendment.

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Executive and the Company hereby amend the Employment Agreement as follows, effective as of the Effective Date set forth above:

1. The second paragraph of Section 4(a)(i) of the Employment Agreement is hereby amended and restated in its entirety as follows:

"For the purposes of this Agreement, the "**Minimum Financial Milestone Event**" shall mean the sale by the Company of its Equity Securities in a bona fide equity financing following the Effective Date in which the Company receives gross proceeds of not less than $5,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. "Equity Securities" means the Company's common stock or preferred stock, or any other securities convertible into the Company's common stock or preferred stock (e.g., convertible promissory notes), issued to one or more third parties for bona fide equity financing purposes. The "**Second Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $10,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The Second Financial Milestone Event will also include any proceeds received from sale of assets, out-licensing and/or partnering agreements. The "**Third Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event and the Second Financial Milestone Event) in which the Company receives aggregate gross proceeds of at least $25,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The Third Financial Milestone Event will also include any proceeds received from sale of assets, out-licensing and/or partnering agreements. The "**Fourth Financial Milestone Event**" shall mean the sale or sales by the Company of its Equity Securities following the Effective Date in a bona fide equity financing (or series of bona fide equity financings, including the Minimum Financial Milestone Event, the Second Financial Milestone Event and the Third Financial Milestone Event, as applicable) in which the Company receives aggregate gross proceeds of at least $45,000,000, including proceeds received in connection with any transaction in which the Company's securities (or the securities of any successor to the Company) become publicly tradeable. The Fourth Financial Milestone Event will also include any proceeds received from sale of assets, out-licensing and/or partnering agreements. For purposes of clarity, the amount of the Minimum Financial Milestone Event shall be included in calculating the Second Financial Milestone Event; the amount of the Minimum Financial Milestone Event and the Second Financial Milestone Event shall be included in calculating the Third Financial Milestone Event; and the amount of the Minimum Financial Milestone Event, the Second Financial Milestone Event and the Third Financial Milestone shall be included in calculating the Fourth Financial Milestone Event.

2. This Third Amendment is hereby incorporated into and forms a part of the Employment Agreement.

3. Except as modified herein, all other terms and conditions of the Employment Agreement, as amended, shall continue in full force and effect.

4. This Third Amendment shall be binding upon the Parties hereto and upon their respective heirs, legal representatives, successors and permitted assigns and shall be governed by and construed in accordance with the laws of the State of North Carolina.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Third Amendment as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Sandeep Laumas
Sandeep Laumas, Executive Chairman

EXECUTIVE:

By: /s/ Jay P. Madan
Jay P. Madan

Address:

Exhibit 10.23

Execution Copy

EXECUTIVE EMPLOYMENT AGREEMENT

THIS EXECUTIVE EMPLOYMENT AGREEMENT (the "**Agreement**"), is entered into as of March 9, 2018 (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and June S. Almenoff, MD, PhD (the "**Executive**").

WITNESSETH:

WHEREAS, the Company wishes to employ the Executive, and the Executive desires to accept employment with the Company, upon the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the foregoing, of the mutual promises herein, and of other good and valuable consideration, including the employment of the Executive by the Company and the compensation to be received by the Executive from the Company from time to time, and specifically the compensation to be received by the Executive pursuant to Section 4 hereof, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending legally to be bound, hereby agree as follows:

1. Employment. As of the Effective Date, the Company hereby employs the Executive and the Executive hereby accepts employment as the Chief Medical Officer ("**CMO**") and Chief Operating Officer ("**COO**") of the Company upon the terms and conditions of this Agreement. The Executive shall report to the Chief Executive Officer ("**CEO**") of the Company. As of the Effective Date, the parties agree that the Agreement for Consulting Services dated January 4, 2018, between the Parties shall terminate.

2. Duties.

(a) The Executive shall faithfully perform all duties of the Company related to the position or positions held by the Executive, including but not limited to all duties set forth in this Agreement and/or in the Bylaws of the Company related to the position or positions held by the Executive and all additional duties that are prescribed from time to time by the Board or other designated officers of the Company, such as the CEO and the Executive Chairman ("**EC**"). The Executive shall devote the Executive's full time and attention to the performance of the Executive's duties and responsibilities on behalf of the Company and in furtherance of its best interests; provided, however, that the Executive, subject to the Executive's obligations hereunder, shall also be permitted to make personal investments, perform reasonable volunteer services and, with the written prior consent of the Company, serve on outside boards of directors for non-profit or for profit corporations. The Company is aware that Executive is currently serving on some outside boards, and the Company and Executive will discuss and agree in writing about whether and on what basis Executive will continue in such roles. The Executive shall comply with all written Company policies, standards, rules and regulations (the "**Company Policies**") and all applicable government laws, rules and regulations that are now or hereafter in effect. The Executive acknowledges receipt of copies of all written Company Policies that are in effect as of the date of this Agreement.

(b) Executive's base of operation shall be in the Company's offices in Raleigh, North Carolina, subject to reasonable business travel and reasonable telecommuting.

3. Term. The term of this Agreement shall continue until terminated by either party as set forth in Section 5 of this Agreement (the "**Term**").

4. Compensation. During the Term, as compensation for the services rendered by the Executive under this Agreement, the Executive shall be entitled to receive the following (all payments are subject to applicable withholdings):

(a) Base Salary. Executive shall be paid an annual salary in the amount of $320,000 (less applicable withholdings), which shall be payable in accordance with the then-current payroll schedule of the Company (the "**Base Salary**"). The Executive's salary will be reviewed periodically and may be increased from time to time by the Company at its discretion.

(b) Bonuses. Executive shall be eligible to participate in any bonus or similar incentive plan adopted by the Company as approved by the Board of Directors ("**Board**") for executives at Executive's level. The amount awarded, if any, to the Executive under any bonus or incentive plan shall be in the discretion of the Board or any committee administering such plan. Executive's bonus, if any, shall be subject to the terms and conditions of any plan or program adopted or approved by the Board.

(c) Equity. Executive shall be eligible to participate in any equity compensation plan or similar program adopted by the Company when approved by the Board and, if applicable, the Company's shareholders, for executives at Executive's level. The amount awarded, if any, to the Executive under any such plan shall be in the discretion of the Board or any committee administering such plan and shall be subject to the terms and conditions of any plan or program adopted or approved by the Board. Subject to the approval of the appropriate plan, as noted above, and the approval of the specific grant by the Board, the Company will make an initial grant to Executive of 700,000 options to purchase shares of common stock of the Company, priced at fair market value at the time of grant. Such grant will be effective when made, following approval by the Board, and shall be subject to terms and conditions to be imposed by the Board under its plans or programs, which the parties anticipate will include, among other things: (i) vesting on a monthly basis over a four (4) year period conditioned upon continued employment with the Company, with 10% of such grant vesting as of the effective date of such grant; and (ii) all unvested options will immediately vest in full upon the occurrence of a change in control that will be defined in the equity plan document that will be developed.

(d) Benefits. The Executive shall be entitled to receive those benefits provided from time to time to other executive employees of the Company, in accordance with the terms and conditions of the applicable plan documents; provided that the Executive meets the eligibility requirements thereof. All such benefits are subject to amendment or termination from time to time by the Company without the consent of the Executive or any other employee of the Company.

(e) Paid Time Off. The Executive shall be entitled to four weeks of paid time off ("**PTO**") to be taken in accordance with the Company's standard PTO policies.

(f) Business Expenses. The Company will reimburse Executive for reasonable travel, entertainment, and other expenses incurred by Executive in the furtherance of the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy for senior executives as in effect from time to time. Provided, however, that the Company will make the reimbursement only if the corresponding expense is incurred during the term of this Agreement and the reimbursement is made on or before the last day of the calendar year following the calendar year in which the expense is incurred, the amount of expenses eligible for such reimbursement during a calendar year will not affect the amount of expenses eligible for such reimbursement in another calendar year, and the right to such reimbursement is not subject to liquidation or exchange for another benefit from the Company.

5. Termination. This Agreement and the Executive's employment by the Company shall or may be terminated, as the case may be, as follows:

(a) Termination by the Executive. The Executive may terminate this Agreement and Executive's employment by the Company:

(i) for "Good Reason" (as defined herein). For purposes of this Agreement, "**Good Reason**" shall mean, the existence, without the consent of the Executive, of any of the following events: (A) the Executive's duties and responsibilities are substantially reduced or diminished; (B) the Executive's base salary is reduced by more than 15% from the level prior to such reduction, except for an across the board reduction in base salary for all executive officers (C) the Company materially breaches its obligations under this Agreement; or (D) the Executive's place of employment is relocated by more than 50 miles. In addition to any requirements set forth above, in order for any of the above events to constitute "Good Reason", the Executive must (X) inform the Company of the existence of the event within 90 days of the initial existence of the event, after which date the Company shall have no less than 30 days to cure the event which otherwise would constitute "Good Reason" hereunder and (Y) the Executive must terminate employment with the Company for such "Good Reason" no later than two years after the initial existence of the event which prompted the Executive's termination.

(ii) Other than for Good Reason 30 days after notice to the Company.

(b) Termination by the Company. The Company may terminate this Agreement and the Executive's employment by the Company upon notice to the Executive (or personal representative):

(i) at any time and for any reason;

(ii) upon the death of the Executive, in which case this Agreement shall terminate immediately; provided that, such termination shall not prejudice any benefits payable to the Executive's spouse or beneficiaries which are fully vested as of the date of death;

(iii) if the Executive is "permanently disabled" (as defined herein), in which case this Agreement shall terminate immediately; provided that, such termination shall not prejudice any benefits payable to the Executive, the Executive's spouse or beneficiaries which are fully vested as of the date of the termination of this Agreement. For purposes of this Agreement, the Executive shall be considered "**permanently disabled**" when a qualified medical doctor mutually acceptable to the Company and the Executive or the Executive's personal representative shall have certified in writing that: (A) the Executive is unable, because of a medically determinable physical or mental disability, to perform substantially all of the Executive's duties, with or without a reasonable accommodation, for more than 180 calendar days measured from the last full day of work; or (B) by reason of mental or physical disability, it is unlikely that the Executive will be able, within 180 calendar days, to resume substantially all business duties and responsibilities in which the Executive was previously engaged and otherwise discharge the Executive's duties under this Agreement; or

(iv) "for cause" (as defined herein). "**For cause**" shall be determined by the Company and shall mean:

A. Any material breach of the terms of this Agreement by the Executive, or the material failure of the Executive to diligently perform the Executive's duties for the Company or the Executive's material failure to achieve her objectives specified by the Board; provided, however, that the Company must first provide Executive with written notice of the grounds under this Section 5(b)(iv)(A) and a period of ten (10) business days in which to cure such grounds;

B. The Executive's unauthorized use of the Company's tangible or intangible property (excluding incidental use) or Executive's breach of the Proprietary Information Agreement (as defined herein) or any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation;

C. Any material failure to comply with material Company Policies, applicable government laws, rules and regulations and/or directives of the Board;

D. The Executive's use of illegal drugs or any illegal substance, or the Executive's use of alcohol in any manner that materially interferes with the performance of the Executive's duties under this Agreement;

E. Any dishonest or illegal action (including, without limitation, embezzlement) or any other action whether or not dishonest or illegal by the Executive which is materially detrimental to the interest and well-being of the Company, including, without limitation, harm to its reputation;

F. The Executive's failure to fully disclose any material conflict of interest that the Executive may have with the Company in a transaction between the Company and any third party which is materially detrimental to the interest and well-being of the Company; or

G. Any adverse action or omission by the Executive which would be required to be disclosed pursuant to public securities laws or which would limit the ability of the Company or any entity affiliated with the Company to sell securities under any Federal or state law or which would disqualify the Company or any affiliated entity from any exemption otherwise available to it.

(c) Obligations of the Company Upon Termination.

(i) Upon the termination of this Agreement: (A) by the Executive pursuant to paragraph 5(a)(ii); or (B) by the Company pursuant to paragraph 5(b)(ii), (iii), or (iv) the Company shall have no further obligations hereunder other than the payment of all compensation and other benefits payable to the Executive through the date of such termination which shall be paid on or before the Company's next regularly scheduled payday unless such amount is not then-calculable, in which case payment shall be made on the first regularly scheduled payday after the amount is calculable.

(ii) Upon termination of this Agreement: (A) by the Executive pursuant to paragraph 5(a)(i); or (B) by the Company pursuant to paragraph 5(b)(i) and provided that the Executive first executes and does not revoke a release and settlement agreement in the form acceptable to the Company within the time period then-specified by the Company but in any event no later than sixty (60) days after the date of termination (the "**Release**"): (1) the Company shall pay the Executive an amount equal to twelve (12) months of Executive's then-current Base Salary (less all applicable deductions) payable in installments in accordance with the then-current generally applicable payroll schedule of the Company commencing on the first regularly scheduled pay date of the Company processed after Executive has executed, delivered to the Company and not revoked the Release; (2) conditioned on Executive's proper and timely election to continue the Company's health insurance benefits under COBRA, or under applicable state law, reimbursement of the additional costs incurred by Executive for continuing such benefits at the same level in which Executive participated prior to the date Executive's employment terminated for the shorter of (a) to twelve (12) months from the date of termination or (b) until the Executive obtains reasonably comparable coverage, with such reimbursements to begin at the same time as severance pay set forth in Section 5(c)(ii)(A).

(d) Resignation as Officer and Director. Upon termination of this Agreement and the Executive's employment hereunder for any reason by either party, the Executive shall be deemed to have resigned from all offices and positions the Executive may hold with the Company at such time including without limitation Board membership and/or positions as an officer of the Company.

6. Proprietary Information Agreement. The terms of the Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement by and between the Company and the Executive, entered into simultaneously herewith (the "**Proprietary Information Agreement**") and any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation between the Company and the Executive, are hereby incorporated by reference and are a material part of this Agreement.

7. Representations and Warranties.

(a) The Executive represents and warrants to the Company that the Executive's performance of this Agreement and as an employee of the Company does not and will not breach any noncompetition agreement or any agreement to keep in confidence proprietary information acquired by the Executive in confidence or in trust prior to the Executive's employment by the Company. The Executive represents and warrants to the Company that the Executive has not entered into, and agrees not to enter into, any agreement that conflicts with or violates this Agreement.

(b) The Executive represents and warrants to the Company that the Executive has not brought and shall not bring with the Executive to the Company, or use in the performance of the Executive's responsibilities for the Company, any materials or documents of a former employer which are not generally available to the public or which did not belong to the Executive prior to the Executive's employment with the Company, unless the Executive has obtained written authorization from the former employer or other owner for their possession and use and provided the Company with a copy thereof.

8. Indemnification.

(a) By the Employee. The Executive shall indemnify and hold harmless the Company, its directors, officers, stockholders, agents, and employees against all claims, costs, expenses, liabilities, and lost profits, including amounts paid in settlement, incurred by any of them as a result of Executive engaging in actions that constitute Cause under Section 5(b)(iv)B, E, F or G of this Agreement or the breach by the Executive of any provision of Section 6 and/or 7 of this Agreement.

(b) By the Company. The Company will indemnify and hold harmless the Executive from any liabilities and expenses arising from Executive's actions as an officer, director or employee of the Company to the fullest extent permitted by law, excepting any unauthorized acts, intentional or illegal conduct which breaches the terms of this or any other agreement or Company policy, including but not limited to the Proprietary Information Agreement.

9. Notices. All notices, requests, consents, approvals, and other communications to, upon, and between the parties shall be in writing and shall be deemed to have been given, delivered, made, and received when: (a) personally delivered; (b) deposited for next day delivery by Federal Express, or other similar overnight courier services; (c) transmitted via telefacsimile or other similar device to the attention of the Company President with receipt acknowledged; or (d) three days after being sent or mailed by certified mail, postage prepaid and return receipt requested, addressed to the Company at 8480 Honeycutt Road, Suite 120, Raleigh, NC 27615, and to the Executive at the address set forth by the signature page below.

10. Effect. This Agreement may be assigned by the Company to its successors in interests. This Agreement shall be binding on and inure to the respective benefit of the Company and its successors and assigns and the Executive and Executive's personal representatives**.**

11. Entire Agreement. This Agreement and the Proprietary Information Agreement and any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation constitute the entire agreement between the parties with respect to the matters set forth herein and supersede all prior agreements and understandings between the parties with respect to the same.

12. Severability. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision.

13. Amendment and Waiver. A waiver of any breach of this Agreement shall not constitute a waiver of any other provision of this Agreement or any subsequent breach of this Agreement. No provision of this Agreement may be amended, modified, deleted, or waived in any manner except by a written agreement executed by the parties.

14. Section 409A Matters. This Agreement is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended and the Treasury Regulations and other applicable guidance thereunder ("**Section 409A**"). To the extent that there is any ambiguity as to whether this Agreement (or any of its provisions) contravenes one or more requirements of Section 409A, such provision shall be interpreted and applied in a matter that does not result in a Section 409A violation. Without limiting the generality of the above:

(a) For clarity, the severance benefits specified in this Agreement (the "**Severance Benefits**") are only payable upon a "separation from service" as defined in Section 409A. The Severance Benefits shall be deemed to be series of separate payments, with each installment being treated as a separate payment. The time and form of payment of any compensation may not be deferred or accelerated to the extent it would result in an impermissible acceleration or deferral under Section 409A.

(b) To the extent this Agreement contains payments which are subject to Section 409A (as opposed to exempt from Section 409A), the Executive's rights to such payments are not subject to anticipation, alienation, sale, transfer, pledge, encumbrance, attachment or garnishment and, where applicable, may only be transferred by will or the laws of descent and distribution.

(c) To the extent the Severance Benefits are intended to be exempt from Section 409A as a result of an "involuntary separation from service" under Section 409A, if all conditions necessary to establish the Executive's entitlement to such Severance Benefits have been satisfied, all Severance Benefits shall be paid or provided in full no later than December 31st of the second calendar year following the calendar year in which the Executive's employment terminated unless another time period is applicable.

(d) If the Employee is a "specified employee" (as defined in Section 409A) on the termination date and a delayed payment is required by Section 409A to avoid a prohibited distribution under Section 409A, then no Severance Benefits that constitute "non-qualified deferred compensation" under Section 409A shall be paid until the earlier of (i) the first day of the 7th month following the date of Employee's "separation from service" as defined in Section 409A, or (ii) the date of Employee's death. Upon the expiration of the applicable deferral period, all payments deferred under this clause shall be paid in a lump sum and any remaining severance benefits shall be paid per the schedule specified in this Agreement.

(e) The Company makes no representation that this Agreement will be exempt from or compliant with Section 409A and makes no affirmative undertaking to preclude Section 409A from applying, but does reserve the right to unilaterally amend this Agreement as may be necessary or advisable to permit the Agreement to be in documentary and operational compliance with Section 409A which determination will be made in the sole discretion of the Company.

15. Governing Law. This Agreement shall be construed, interpreted, and governed in accordance with and by North Carolina law and the applicable provisions of federal law ("Applicable Federal Law"). Any and all claims, controversies, and causes of action arising out of or relating to this Agreement, whether sounding in contract, tort, or statute, shall be governed by the laws of the state of North Carolina, including its statutes of limitations, except for Applicable Federal Law, without giving effect to any North Carolina conflict-of-laws rule that would result in the application of the laws of a different jurisdiction. Both Executive and the Company acknowledge and agree that the state or federal courts located in North Carolina have personal jurisdiction over them and over any dispute arising under this Agreement, and both Executive and the Company irrevocably consent to the jurisdiction of such courts.

16. Consent to Jurisdiction and Venue. Each of the parties agrees that any suit, action, or proceeding arising out of this Agreement may be instituted against it in the state or federal courts located in Wake County, North Carolina. Each of the parties hereby waives any objection that it may have to the venue of any such suit, action, or proceeding, and each of the parties hereby irrevocably consents to the personal jurisdiction of any such court in any such suit, action, or proceeding.

17. Counterparts. This Agreement may be executed in more than one counterpart, each of which shall be deemed an original, and all of which shall be deemed a single agreement**.**

18. Headings. The headings herein are for convenience only and shall not affect the interpretation of this Agreement.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Christopher Prior

JUNE S. ALMENOFF, MD, PhD

/s/ June S. Almenoff

Address:

Exhibit 10.24

INNOVATE BIOPHARMACEUTICALS, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

February 22, 2018

Non-employee members of the board of directors (the ***"Board"***) of Innovate Biopharmaceuticals, Inc. (the ***"Company"***) shall be eligible to receive cash and equity compensation as set forth in this Non-Employee Director Compensation Policy (this ***"Policy"***). The cash and equity compensation described in this Policy shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a ***"Non-Employee Director"***), who may be eligible to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Policy shall become effective on the date hereof (the ***"Effective Date"***) and shall remain in effect until it is revised or rescinded by further action of the Board. This Policy may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Policy shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors and between any subsidiary of the Company and any of its non-employee directors.

1. Cash Compensation.

(a) Annual Retainers. Each Non-Employee Director shall receive an annual retainer of $40,000 for service on the Board.

(b) Additional Annual Retainers. In addition, a Non-Employee Director shall receive the following annual retainers:

(i) Chairman of the Board. A Non-Employee Director serving as Chairman of the Board shall receive an additional annual retainer of $35,000 for such service.

(ii) Audit Committee. A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of $25,000 for such service. A Non-Employee Director serving as a member of the Audit Committee (other than the Chairperson) shall receive an additional annual retainer of $7,500 for such service.

(iii) Compensation Committee. A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of $15,000 for such service. A Non-Employee Director serving as a member of the Compensation Committee (other than the Chairperson) shall receive an additional annual retainer of $7,500 for such service.

(iv) Nominating and Corporate Governance Committee. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $15,000 for such service. A Non-Employee Director serving as a member of the Nominating and Corporate Governance Committee (other than the Chairperson) shall receive an additional annual retainer of $7,500 for such service.

(c) Payment of Retainers. The annual retainers described in Sections 1(a) and 1(b) shall be earned on a quarterly basis based on a calendar quarter and shall be due and payable as soon as practicable after the first day of the quarter in which such services are to be rendered (*i.e.*, as soon as practicable after January 1, April 1, July 1 and October 1). In the event a Non-Employee Director is appointed or elected during the course of any quarter, such Non-Employee Director shall receive a prorated portion of the retainer(s) otherwise payable to such Non-Employee Director for such calendar quarter pursuant to Sections 1(a) and 1(b), with such prorated portion determined by multiplying such otherwise payable retainer(s) by a fraction, the numerator of which is the number of days during which the Non-Employee Director serves as a Non-Employee Director or in the applicable positions described in Section 1(b) during the applicable calendar quarter and the denominator of which is the number of days in the applicable calendar quarter.

2. Equity Compensation. Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of any applicable Company equity incentive plan then-maintained by the Company (the ***"Equity Plan"***) and shall be granted subject to the execution and delivery of award agreements, including attached exhibits, in substantially the forms previously approved by the Board. All applicable terms of the Equity Plan apply to this Policy as if fully set forth herein, and all equity grants hereunder are subject in all respects to the terms of the Equity Plan. Notwithstanding anything else to the contrary herein, awards shall only be made pursuant to this policy if there are sufficient authorized but unissued shares reserved under the Equity Plan for such awards. If there are not sufficient authorized but unissued shares so reserved, the awards shall be made as soon as reasonably practicable after a sufficient number of additional shares become available under the Equity Plan for such awards.

(a) Annual Awards. A Non-Employee Director who (i) serves on the Board as of the date of any annual meeting of the Company's stockholders (an ***"Annual Meeting"***) after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such Annual Meeting shall be automatically granted, on the date of such Annual Meeting, an option to purchase the number of shares of the Company's common stock (at a per-share exercise price equal to the closing price per share of the Company's common stock on the date of such annual meeting (or on the last preceding trading day if the date of the annual meeting is not a trading day) that have an aggregate fair value on the date of grant of $75,000 (or in the case of the Chairman of the Board, $125,000) (as determined in accordance with ASC 718) (with the number of shares of Common Stock underlying each such award subject to adjustment as provided in the Equity Plan). At such Non-Employee Director's written election at least 30 days prior to the date of grant, such grant may instead be in the form of restricted stock units of the Company having equivalent value (using the Black Scholes valuation methodology) to the value of the annual award to be paid. Any such election will remain in effect until revoked by such Non-Employee Director, provided that any such revocation is made at least 30 days prior to the date of grant. The awards described in this Section 2(a) shall be referred to as the ***"Annual Awards."*** For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an Annual Meeting shall only receive an Annual Award in connection with such election, and shall not receive any Initial Award (as defined below) on the date of such Annual Meeting as well.

(b) Initial Awards. Except as otherwise determined by the Board, each Non-Employee Director who is initially elected or appointed to the Board on any date other than the date of an Annual Meeting (including directors appointed to the Board in connection with the consummation of the Company's reverse merger transaction on January 29, 2018, to the extent such individual has not been previously granted an award in anticipation of Board service) shall be automatically granted, on the date of such Non-Employee Director's initial election or appointment (such Non-Employee Director's ***"Start Date"***), an option to purchase shares of the Company's common stock (at a per-share exercise price equal to the closing price per share of the Company's common stock on the date of such election or appointment (or on the last preceding trading day if such date is not a trading day) that have an aggregate fair value on such Non-Employee Director's Start Date equal to the product of (i) $75,000 (or in the case of the Chairman of the Board, $125,000) (as determined in accordance with ASC 718), and (ii) a fraction, the numerator of which is (x) 365 minus (y) the number of days in the period beginning on the date of the Annual Meeting immediately preceding such Non-Employee Director's Start Date and ending on such Non-Employee Director's Start Date (or, with respect to Initial Awards granted to directors appointed to the Board in connection with the consummation of the Company's reverse merger transaction on January 29, 2018, zero) and the denominator of which is 365 (with the number of shares of Common Stock underlying each such award subject to adjustment as provided in the Equity Plan). At such Non-Employee Director's written election before the date of grant, such grant may instead be in the form of restricted stock units of the Company having equivalent value (using the Black Scholes valuation methodology) to the value of the annual award to be paid. The awards described in this Section 2(b) shall be referred to as ***"Initial Awards."*** For the avoidance of doubt, no Non-Employee Director shall be granted more than one Initial Award.

(c) Termination of Service of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section 2(b) above, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from service with the Company and any parent or subsidiary of the Company, Annual Awards as described in Section 2(a) above.

(d) Vesting of Awards Granted to Non-Employee Directors. Each Initial Award shall vest in full on the date that is the one year anniversary of the date of grant. Each Annual Award shall vest and become exercisable in 12 equal monthly installments, such that each such award shall be fully vested and exercisable on the first anniversary of the date of grant. In all cases, vesting shall be subject to the Non-Employee Director's continued service on the Board as a Non-Employee Director through each applicable vesting date. No portion of an Annual Award or Initial Award that is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall become vested and exercisable thereafter. All of a Non-Employee Director's Annual Awards and Initial Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

* * * * *

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement ("Restated Agreement") is executed on the 11th day of March, 2018 (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Sandeep Laumas, MD (the "**Executive**"). The Executive and the Company may be referred to herein as a "**Party**" or collectively as the "**Parties**."

W I T N E S S E T H:

Executive has been employed by privately held Innovate Biopharmaceuticals Inc. ("**Private Innovate**") in the role of Executive Chairman of the Board of Directors, subject to the terms of an Executive Employment Agreement, dated October 28, 2015, as amended on February 26, 2016, March 1, 2017, and August 31, 2017 (collectively the "**Prior Agreement**").

On January 29, 2018, Monster Digital, Inc. ("**Monster**"), and Private Innovate completed a reverse recapitalization in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated July 3, 2017 (the "**Merger Agreement**"), by and among Monster, Monster Merger Sub, Inc. ("**Merger Sub**") and Private Innovate, which changed its name in connection with the transaction to IB Pharmaceuticals Inc. ("**IB Pharmaceuticals**"). Pursuant to the Merger Agreement, Merger Sub merged with and into IB Pharmaceuticals with IB Pharmaceuticals surviving as the wholly owned subsidiary of Monster (the "**Merger**"). Immediately following the Merger, Monster changed its name to the Company.

Both Executive and the Company wish to continue the employment relationship on the updated terms set forth in this Restated Agreement, which provide Executive with greater benefits than those under his Prior Agreement. This Restated Agreement is intended to replace and supersede the Prior Employment Agreement.

In consideration of the foregoing, of the mutual promises herein, and of other good and valuable consideration, including the continued employment of the Executive by the Company and the compensation to be received by the Executive from the Company from time to time, and specifically the compensation to be received by the Executive pursuant to Section 4 hereof, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending legally to be bound, hereby agree as follows:

1. Employment. As of the Effective Date, the Company hereby continues to employ the Executive and the Executive hereby accepts employment as the Executive Chairman of the Board of Directors (the "**Chairman**") of the Company upon the terms and conditions of this Restated Agreement. The Executive shall report to the Board of Directors ("**Board**") of the Company. As of the Effective Date, the parties agree that the Prior Agreement between the Parties shall terminate.

2. Duties.

(a) The Executive shall faithfully perform all duties of the Company related to the position or positions held by the Executive, including but not limited to all duties set forth in this Restated Agreement and/or in the Bylaws of the Company related to the position or positions held by the Executive and all additional duties that are prescribed from time to time by the Board. The Executive shall devote the Executive's full time and attention to the performance of the Executive's duties and responsibilities on behalf of the Company and in furtherance of its best interests; provided, however, that the Executive, subject to the Executive's obligations hereunder, shall also be permitted to make personal investments, perform reasonable volunteer services and, with the written prior consent of the Company, serve on outside boards of directors for non-profit or for profit corporations. The Executive shall comply with all written Company policies, standards, rules and regulations (the "**Company Policies**") and all applicable government laws, rules and regulations that are now or hereafter in effect. The Executive acknowledges receipt of copies of all written Company Policies that are in effect as of the date of this Restated Agreement.

(b) Executive's base of operation shall be Old Greenwich, CT, subject to reasonable business travel.

3. Term. The term of this Restated Agreement shall continue until terminated by either party as set forth in Section 5 of this Restated Agreement (the "**Term**").

4. Compensation. During the Term, as compensation for the services rendered by the Executive under this Restated Agreement, the Executive shall be entitled to receive the following (all payments are subject to applicable withholdings):

(a) Base Salary. Executive shall be paid an annual salary in the amount of $275,000 (less applicable withholdings), to be retroactively effective as of March 1, 2018, which shall be payable in accordance with the then-current payroll schedule of the Company (the "**Base Salary**"). The Executive's salary will be reviewed periodically and may be increased from time to time by the Company at its discretion.

(b) Bonuses. Executive shall be eligible to participate in any bonus or similar incentive plan adopted by the Company as approved by the Board of Directors ("**Board**") for executives at Executive's level. The amount awarded, if any, to the Executive under any bonus or incentive plan shall be in the discretion of the Board or any committee administering such plan. Executive's bonus, if any, shall be subject to the terms and conditions of any plan or program adopted or approved by the Board.

(c) Equity. Executive shall be eligible to participate in any equity compensation plan or similar program adopted by the Company when approved by the Board and, if applicable, the Company's shareholders, for executives at Executive's level. The amount awarded, if any, to the Executive under any such plan shall be in the discretion of the Board or any committee administering such plan and shall be subject to the terms and conditions of any plan or program adopted or approved by the Board.

(d) Benefits. The Executive shall be entitled to receive those benefits provided from time to time to other executive employees of the Company, in accordance with the terms and conditions of the applicable plan documents; provided that the Executive meets the eligibility requirements thereof. All such benefits are subject to amendment or termination from time to time by the Company without the consent of the Executive or any other employee of the Company.

(e) Paid Time Off. The Executive shall be entitled to four weeks of paid time off ("**PTO**") to be taken in accordance with the Company's standard PTO policies.

(f) Business Expenses. The Company will reimburse Executive for reasonable travel, entertainment, and other expenses incurred by Executive in the furtherance of the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy for senior executives as in effect from time to time. Provided, however, that the Company will make the reimbursement only if the corresponding expense is incurred during the term of this Restated Agreement and the reimbursement is made on or before the last day of the calendar year following the calendar year in which the expense is incurred, the amount of expenses eligible for such reimbursement during a calendar year will not affect the amount of expenses eligible for such reimbursement in another calendar year, and the right to such reimbursement is not subject to liquidation or exchange for another benefit from the Company.

5. Termination. This Restated Agreement and the Executive's employment by the Company shall or may be terminated, as the case may be, as follows:

(a) Termination by the Executive. The Executive may terminate this Restated Agreement and Executive's employment by the Company:

(i) for "Good Reason" (as defined herein). For purposes of this Restated Agreement, "**Good Reason**" shall mean, the existence, without the consent of the Executive, of any of the following events: (A) the Executive's duties and responsibilities are substantially reduced or diminished; (B) the Executive's base salary is reduced by more than 15% from the level prior to such reduction, except for an across the board reduction in base salary for all executive officers (C) the Company materially breaches its obligations under this Restated Agreement; or (D) the Executive's place of employment is relocated by more than 50 miles. In addition to any requirements set forth above, in order for any of the above events to constitute "Good Reason", the Executive must (X) inform the Company of the existence of the event within 90 days of the initial existence of the event, after which date the Company shall have no less than 30 days to cure the event which otherwise would constitute "Good Reason" hereunder and (Y) the Executive must terminate employment with the Company for such "Good Reason" no later than two years after the initial existence of the event which prompted the Executive's termination.

(ii) Other than for Good Reason 30 days after notice to the Company.

(b) Termination by the Company. The Company may terminate this Restated Agreement and the Executive's employment by the Company upon notice to the Executive (or personal representative):

(i) at any time and for any reason;

(ii) upon the death of the Executive, in which case this Restated Agreement shall terminate immediately; provided that, such termination shall not prejudice any benefits payable to the Executive's spouse or beneficiaries which are fully vested as of the date of death;

(iii) if the Executive is “permanently disabled” (as defined herein), in which case this Restated Agreement shall terminate immediately; provided that, such termination shall not prejudice any benefits payable to the Executive, the Executive’s spouse or beneficiaries which are fully vested as of the date of the termination of this Restated Agreement. For purposes of this Restated Agreement, the Executive shall be considered “**permanently disabled**” when a qualified medical doctor mutually acceptable to the Company and the Executive or the Executive’s personal representative shall have certified in writing that: (A) the Executive is unable, because of a medically determinable physical or mental disability, to perform substantially all of the Executive’s duties, with or without a reasonable accommodation, for more than 180 calendar days measured from the last full day of work; or (B) by reason of mental or physical disability, it is unlikely that the Executive will be able, within 180 calendar days, to resume substantially all business duties and responsibilities in which the Executive was previously engaged and otherwise discharge the Executive’s duties under this Restated Agreement; or

(iv) "for cause" (as defined herein). “**For cause**” shall be determined by the Company and shall mean:

A. Any material breach of the terms of this Restated Agreement by the Executive, or the material failure of the Executive to diligently perform the Executive’s duties for the Company or the Executive’s material failure to achieve her objectives specified by the Board; provided, however, that the Company must first provide Executive with written notice of the grounds under this Section 5(b)(iv)(A) and a period of ten (10) business days in which to cure such grounds;

B. The Executive’s unauthorized use of the Company’s tangible or intangible property (excluding incidental use) or Executive’s breach of the Proprietary Information Agreement (as defined herein) or any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation;

C. Any material failure to comply with material Company Policies, applicable government laws, rules and regulations and/or directives of the Board;

D. The Executive’s use of illegal drugs or any illegal substance, or the Executive’s use of alcohol in any manner that materially interferes with the performance of the Executive’s duties under this Restated Agreement;

E. Any dishonest or illegal action (including, without limitation, embezzlement) or any other action whether or not dishonest or illegal by the Executive which is materially detrimental to the interest and well-being of the Company, including, without limitation, harm to its reputation;

F. The Executive's failure to fully disclose any material conflict of interest that the Executive may have with the Company in a transaction between the Company and any third party which is materially detrimental to the interest and well-being of the Company; or

G. Any adverse action or omission by the Executive which would be required to be disclosed pursuant to public securities laws or which would limit the ability of the Company or any entity affiliated with the Company to sell securities under any Federal or state law or which would disqualify the Company or any affiliated entity from any exemption otherwise available to it.

(c) Obligations of the Company Upon Termination.

(i) Upon the termination of this Restated Agreement: (A) by the Executive pursuant to paragraph 5(a)(ii); or (B) by the Company pursuant to paragraph 5(b)(ii), (iii), or (iv) the Company shall have no further obligations hereunder other than the payment of all compensation and other benefits payable to the Executive through the date of such termination which shall be paid on or before the Company's next regularly scheduled payday unless such amount is not then-calculable, in which case payment shall be made on the first regularly scheduled payday after the amount is calculable.

(ii) Upon termination of this Restated Agreement: (A) by the Executive pursuant to paragraph 5(a)(i); or (B) by the Company pursuant to paragraph 5(b)(i) and provided that the Executive first executes and does not revoke a release and settlement agreement in the form acceptable to the Company within the time period then-specified by the Company but in any event no later than sixty (60) days after the date of termination (the "**Release**"): (1) the Company shall pay the Executive an amount equal to twelve (12) months of Executive's then-current Base Salary (less all applicable deductions) payable in installments in accordance with the then-current generally applicable payroll schedule of the Company commencing on the first regularly scheduled pay date of the Company processed after Executive has executed, delivered to the Company and not revoked the Release; (2) conditioned on Executive's proper and timely election to continue the Company's health insurance benefits under COBRA, or under applicable state law, reimbursement of the additional costs incurred by Executive for continuing such benefits at the same level in which Executive participated prior to the date Executive's employment terminated for the shorter of (a) to twelve (12) months from the date of termination or (b) until the Executive obtains reasonably comparable coverage, with such reimbursements to begin at the same time as severance pay set forth in Section 5(c)(ii)(A).

(d) Resignation as Officer and Director. Upon termination of this Restated Agreement and the Executive's employment hereunder for any reason by either party, the Executive shall be deemed to have resigned from all offices and positions the Executive may hold with the Company at such time including without limitation Board membership and/or positions as an officer of the Company.

6. Proprietary Information Agreement. The terms of the Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement by and between the Company and the Executive, entered into simultaneously herewith (the "**Proprietary Information Agreement**") and any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation between the Company and the Executive, are hereby incorporated by reference and are a material part of this Restated Agreement.

7. Representations and Warranties.

(a) The Executive represents and warrants to the Company that the Executive's performance of this Restated Agreement and as an employee of the Company does not and will not breach any noncompetition agreement or any agreement to keep in confidence proprietary information acquired by the Executive in confidence or in trust prior to the Executive's employment by the Company. The Executive represents and warrants to the Company that the Executive has not entered into, and agrees not to enter into, any agreement that conflicts with or violates this Restated Agreement.

(b) The Executive represents and warrants to the Company that the Executive has not brought and shall not bring with the Executive to the Company, or use in the performance of the Executive's responsibilities for the Company, any materials or documents of a former employer which are not generally available to the public or which did not belong to the Executive prior to the Executive's employment with the Company, unless the Executive has obtained written authorization from the former employer or other owner for their possession and use and provided the Company with a copy thereof.

8. Indemnification.

(a) By the Employee. The Executive shall indemnify and hold harmless the Company, its directors, officers, stockholders, agents, and employees against all claims, costs, expenses, liabilities, and lost profits, including amounts paid in settlement, incurred by any of them as a result of Executive engaging in actions that constitute Cause under Section 5(b)(iv)B, E, F or G of this Restated Agreement or the breach by the Executive of any provision of Section 6 and/or 7 of this Restated Agreement.

(b) By the Company. The Company will indemnify and hold harmless the Executive from any liabilities and expenses arising from Executive's actions as an officer, director or employee of the Company to the fullest extent permitted by law, excepting any unauthorized acts, intentional or illegal conduct which breaches the terms of this or any other agreement or Company policy, including but not limited to the Proprietary Information Agreement.

9. Notices. All notices, requests, consents, approvals, and other communications to, upon, and between the parties shall be in writing and shall be deemed to have been given, delivered, made, and received when: (a) personally delivered; (b) deposited for next day delivery by Federal Express, or other similar overnight courier services; (c) transmitted via telefacsimile or other similar device to the attention of the Company President with receipt acknowledged; or (d) three days after being sent or mailed by certified mail, postage prepaid and return receipt requested, addressed to the Company at 8480 Honeycutt Road, Suite 120, Raleigh, NC 27615, and to the Executive at the address set forth by the signature page below.

10. Effect. This Restated Agreement may be assigned by the Company to its successors in interests. This Restated Agreement shall be binding on and inure to the respective benefit of the Company and its successors and assigns and the Executive and Executive's personal representatives**.**

11. Entire Agreement. This Restated Agreement and the Proprietary Information Agreement and any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation constitute the entire agreement between the parties with respect to the matters set forth herein and supersede all prior agreements and understandings between the parties with respect to the same.

12. Severability. The invalidity or unenforceability of any provision of this Restated Agreement shall not affect the validity or enforceability of any other provision.

13. Amendment and Waiver. A waiver of any breach of this Restated Agreement shall not constitute a waiver of any other provision of this Restated Agreement or any subsequent breach of this Restated Agreement. No provision of this Restated Agreement may be amended, modified, deleted, or waived in any manner except by a written agreement executed by the parties.

14. Section 409A Matters. This Restated Agreement is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended and the Treasury Regulations and other applicable guidance thereunder ("**Section 409A**"). To the extent that there is any ambiguity as to whether this Restated Agreement (or any of its provisions) contravenes one or more requirements of Section 409A, such provision shall be interpreted and applied in a matter that does not result in a Section 409A violation. Without limiting the generality of the above:

(a) For clarity, the severance benefits specified in this Restated Agreement (the "**Severance Benefits**") are only payable upon a "separation from service" as defined in Section 409A. The Severance Benefits shall be deemed to be series of separate payments, with each installment being treated as a separate payment. The time and form of payment of any compensation may not be deferred or accelerated to the extent it would result in an impermissible acceleration or deferral under Section 409A.

(b) To the extent this Restated Agreement contains payments which are subject to Section 409A (as opposed to exempt from Section 409A), the Executive's rights to such payments are not subject to anticipation, alienation, sale, transfer, pledge, encumbrance, attachment or garnishment and, where applicable, may only be transferred by will or the laws of descent and distribution.

(c) To the extent the Severance Benefits are intended to be exempt from Section 409A as a result of an "involuntary separation from service" under Section 409A, if all conditions necessary to establish the Executive's entitlement to such Severance Benefits have been satisfied, all Severance Benefits shall be paid or provided in full no later than December 31st of the second calendar year following the calendar year in which the Executive's employment terminated unless another time period is applicable.

(d) If the Employee is a "specified employee" (as defined in Section 409A) on the termination date and a delayed payment is required by Section 409A to avoid a prohibited distribution under Section 409A, then no Severance Benefits that constitute "non-qualified deferred compensation" under Section 409A shall be paid until the earlier of (i) the first day of the 7th month following the date of Employee's "separation from service" as defined in Section 409A, or (ii) the date of Employee's death. Upon the expiration of the applicable deferral period, all payments deferred under this clause shall be paid in a lump sum and any remaining severance benefits shall be paid per the schedule specified in this Restated Agreement.

(e) The Company makes no representation that this Restated Agreement will be exempt from or compliant with Section 409A and makes no affirmative undertaking to preclude Section 409A from applying, but does reserve the right to unilaterally amend this Restated Agreement as may be necessary or advisable to permit the Agreement to be in documentary and operational compliance with Section 409A which determination will be made in the sole discretion of the Company.

15. Governing Law. This Restated Agreement shall be construed, interpreted, and governed in accordance with and by North Carolina law and the applicable provisions of federal law ("Applicable Federal Law"). Any and all claims, controversies, and causes of action arising out of or relating to this Restated Agreement, whether sounding in contract, tort, or statute, shall be governed by the laws of the state of North Carolina, including its statutes of limitations, except for Applicable Federal Law, without giving effect to any North Carolina conflict-of-laws rule that would result in the application of the laws of a different jurisdiction. Both Executive and the Company acknowledge and agree that the state or federal courts located in North Carolina have personal jurisdiction over them and over any dispute arising under this Restated Agreement, and both Executive and the Company irrevocably consent to the jurisdiction of such courts.

16. Consent to Jurisdiction and Venue. Each of the parties agrees that any suit, action, or proceeding arising out of this Restated Agreement may be instituted against it in the state or federal courts located in Wake County, North Carolina. Each of the parties hereby waives any objection that it may have to the venue of any such suit, action, or proceeding, and each of the parties hereby irrevocably consents to the personal jurisdiction of any such court in any such suit, action, or proceeding.

17. Counterparts. This Restated Agreement may be executed in more than one counterpart, each of which shall be deemed an original, and all of which shall be deemed a single agreement**.**

18. Headings. The headings herein are for convenience only and shall not affect the interpretation of this Restated Agreement.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Restated Agreement as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Christopher P. Prior, Ph.D.
Name: Christopher P. Prior, Ph.D.
Title: Chief Executive Officer

SANDEEP LAUMAS, MD

/s/ Sandeep Laumas, MD

Address:

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement ("Restated Agreement") is executed on the 11th day of March, 2018 (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Christopher P. Prior, Ph.D. (the "**Executive**"). The Executive and the Company may be referred to herein as a "**Party**" or collectively as the "**Parties**."

W I T N E S S E T H:

Executive has been employed by privately held Innovate Biopharmaceuticals Inc. ("**Private Innovate**") in the role of Chief Executive Officer of the Company, subject to the terms of an Executive Employment Agreement, dated November 2, 2015, as amended on February 26, 2016, March 1, 2017, and August 31, 2017 (collectively the "**Prior Agreement**").

On January 29, 2018, Monster Digital, Inc. ("**Monster**"), and Private Innovate completed a reverse recapitalization in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated July 3, 2017 (the "**Merger Agreement**"), by and among Monster, Monster Merger Sub, Inc. ("**Merger Sub**") and Private Innovate, which changed its name in connection with the transaction to IB Pharmaceuticals Inc. ("**IB Pharmaceuticals**"). Pursuant to the Merger Agreement, Merger Sub merged with and into IB Pharmaceuticals with IB Pharmaceuticals surviving as the wholly owned subsidiary of Monster (the "**Merger**"). Immediately following the Merger, Monster changed its name to the Company.

Both Executive and the Company wish to continue the employment relationship on the updated terms set forth in this Restated Agreement, which provide Executive with greater benefits than those under his Prior Agreement. This Restated Agreement is intended to replace and supersede the Prior Employment Agreement.

In consideration of the foregoing, of the mutual promises herein, and of other good and valuable consideration, including the continued employment of the Executive by the Company and the compensation to be received by the Executive from the Company from time to time, and specifically the compensation to be received by the Executive pursuant to Section 4 hereof, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending legally to be bound, hereby agree as follows:

1. Employment. As of the Effective Date, the Company hereby continues to employ the Executive and the Executive hereby accepts employment as the Chief Executive Officer of the Company (the "**CEO**") upon the terms and conditions of this Restated Agreement. The Executive shall report to the Board of Directors ("**Board**") of the Company. As of the Effective Date, the parties agree that the Prior Agreement between the Parties shall terminate.

2. Duties.

(a) The Executive shall faithfully perform all duties of the Company related to the position or positions held by the Executive, including but not limited to all duties set forth in this Restated Agreement and/or in the Bylaws of the Company related to the position or positions held by the Executive and all additional duties that are prescribed from time to time by the Board. The Executive shall devote the Executive's full time and attention to the performance of the Executive's duties and responsibilities on behalf of the Company and in furtherance of its best interests; provided, however, that the Executive, subject to the Executive's obligations hereunder, shall also be permitted to make personal investments, perform reasonable volunteer services and, with the written prior consent of the Company, serve on outside boards of directors for non-profit or for profit corporations. The Executive shall comply with all written Company policies, standards, rules and regulations (the "**Company Policies**") and all applicable government laws, rules and regulations that are now or hereafter in effect. The Executive acknowledges receipt of copies of all written Company Policies that are in effect as of the date of this Restated Agreement.

(b) Executive's base of operation shall be Rosemont, PA, subject to reasonable business travel.

3. Term. The term of this Restated Agreement shall continue until terminated by either party as set forth in Section 5 of this Restated Agreement (the "**Term**").

4. Compensation. During the Term, as compensation for the services rendered by the Executive under this Restated Agreement, the Executive shall be entitled to receive the following (all payments are subject to applicable withholdings):

(a) Base Salary. Executive shall be paid an annual salary in the amount of $300,000 (less applicable withholdings), to be retroactively effective as of March 1, 2018, which shall be payable in accordance with the then-current payroll schedule of the Company (the "**Base Salary**"). The Executive's salary will be reviewed periodically and may be increased from time to time by the Company at its discretion.

(b) Bonuses. Executive shall be eligible to participate in any bonus or similar incentive plan adopted by the Company as approved by the Board of Directors ("**Board**") for executives at Executive's level. The amount awarded, if any, to the Executive under any bonus or incentive plan shall be in the discretion of the Board or any committee administering such plan. Executive's bonus, if any, shall be subject to the terms and conditions of any plan or program adopted or approved by the Board.

(c) Equity. Executive shall be eligible to participate in any equity compensation plan or similar program adopted by the Company when approved by the Board and, if applicable, the Company's shareholders, for executives at Executive's level. The amount awarded, if any, to the Executive under any such plan shall be in the discretion of the Board or any committee administering such plan and shall be subject to the terms and conditions of any plan or program adopted or approved by the Board.

(d) Benefits. The Executive shall be entitled to receive those benefits provided from time to time to other executive employees of the Company, in accordance with the terms and conditions of the applicable plan documents; provided that the Executive meets the eligibility requirements thereof. All such benefits are subject to amendment or termination from time to time by the Company without the consent of the Executive or any other employee of the Company.

(e) Paid Time Off. The Executive shall be entitled to four weeks of paid time off ("**PTO**") to be taken in accordance with the Company's standard PTO policies.

(f) Business Expenses. The Company will reimburse Executive for reasonable travel, entertainment, and other expenses incurred by Executive in the furtherance of the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy for senior executives as in effect from time to time. Provided, however, that the Company will make the reimbursement only if the corresponding expense is incurred during the term of this Restated Agreement and the reimbursement is made on or before the last day of the calendar year following the calendar year in which the expense is incurred, the amount of expenses eligible for such reimbursement during a calendar year will not affect the amount of expenses eligible for such reimbursement in another calendar year, and the right to such reimbursement is not subject to liquidation or exchange for another benefit from the Company.

5. Termination. This Restated Agreement and the Executive's employment by the Company shall or may be terminated, as the case may be, as follows:

(a) Termination by the Executive. The Executive may terminate this Restated Agreement and Executive's employment by the Company:

(i) for "Good Reason" (as defined herein). For purposes of this Restated Agreement, "**Good Reason**" shall mean, the existence, without the consent of the Executive, of any of the following events: (A) the Executive's duties and responsibilities are substantially reduced or diminished; (B) the Executive's base salary is reduced by more than 15% from the level prior to such reduction, except for an across the board reduction in base salary for all executive officers (C) the Company materially breaches its obligations under this Restated Agreement; or (D) the Executive's place of employment is relocated by more than 50 miles. In addition to any requirements set forth above, in order for any of the above events to constitute "Good Reason", the Executive must (X) inform the Company of the existence of the event within 90 days of the initial existence of the event, after which date the Company shall have no less than 30 days to cure the event which otherwise would constitute "Good Reason" hereunder and (Y) the Executive must terminate employment with the Company for such "Good Reason" no later than two years after the initial existence of the event which prompted the Executive's termination.

(ii) Other than for Good Reason 30 days after notice to the Company.

(b) Termination by the Company. The Company may terminate this Restated Agreement and the Executive's employment by the Company upon notice to the Executive (or personal representative):

(i) at any time and for any reason;

(ii) upon the death of the Executive, in which case this Restated Agreement shall terminate immediately; provided that, such termination shall not prejudice any benefits payable to the Executive's spouse or beneficiaries which are fully vested as of the date of death;

(iii) if the Executive is “permanently disabled” (as defined herein), in which case this Restated Agreement shall terminate immediately; provided that, such termination shall not prejudice any benefits payable to the Executive, the Executive’s spouse or beneficiaries which are fully vested as of the date of the termination of this Restated Agreement. For purposes of this Restated Agreement, the Executive shall be considered “**permanently disabled**” when a qualified medical doctor mutually acceptable to the Company and the Executive or the Executive’s personal representative shall have certified in writing that: (A) the Executive is unable, because of a medically determinable physical or mental disability, to perform substantially all of the Executive’s duties, with or without a reasonable accommodation, for more than 180 calendar days measured from the last full day of work; or (B) by reason of mental or physical disability, it is unlikely that the Executive will be able, within 180 calendar days, to resume substantially all business duties and responsibilities in which the Executive was previously engaged and otherwise discharge the Executive’s duties under this Restated Agreement; or

(iv) "for cause" (as defined herein). “**For cause**” shall be determined by the Company and shall mean:

A. Any material breach of the terms of this Restated Agreement by the Executive, or the material failure of the Executive to diligently perform the Executive’s duties for the Company or the Executive’s material failure to achieve her objectives specified by the Board; provided, however, that the Company must first provide Executive with written notice of the grounds under this Section 5(b)(iv)(A) and a period of ten (10) business days in which to cure such grounds;

B. The Executive’s unauthorized use of the Company’s tangible or intangible property (excluding incidental use) or Executive’s breach of the Proprietary Information Agreement (as defined herein) or any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation;

C. Any material failure to comply with material Company Policies, applicable government laws, rules and regulations and/or directives of the Board;

D. The Executive’s use of illegal drugs or any illegal substance, or the Executive’s use of alcohol in any manner that materially interferes with the performance of the Executive’s duties under this Restated Agreement;

E. Any dishonest or illegal action (including, without limitation, embezzlement) or any other action whether or not dishonest or illegal by the Executive which is materially detrimental to the interest and well-being of the Company, including, without limitation, harm to its reputation;

F. The Executive’s failure to fully disclose any material conflict of interest that the Executive may have with the Company in a transaction between the Company and any third party which is materially detrimental to the interest and well-being of the Company; or

G. Any adverse action or omission by the Executive which would be required to be disclosed pursuant to public securities laws or which would limit the ability of the Company or any entity affiliated with the Company to sell securities under any Federal or state law or which would disqualify the Company or any affiliated entity from any exemption otherwise available to it.

(c) Obligations of the Company Upon Termination.

(i) Upon the termination of this Restated Agreement: (A) by the Executive pursuant to paragraph 5(a)(ii); or (B) by the Company pursuant to paragraph 5(b)(ii), (iii), or (iv) the Company shall have no further obligations hereunder other than the payment of all compensation and other benefits payable to the Executive through the date of such termination which shall be paid on or before the Company's next regularly scheduled payday unless such amount is not then-calculable, in which case payment shall be made on the first regularly scheduled payday after the amount is calculable.

(ii) Upon termination of this Restated Agreement: (A) by the Executive pursuant to paragraph 5(a)(i); or (B) by the Company pursuant to paragraph 5(b)(i) and provided that the Executive first executes and does not revoke a release and settlement agreement in the form acceptable to the Company within the time period then-specified by the Company but in any event no later than sixty (60) days after the date of termination (the "**Release**"): (1) the Company shall pay the Executive an amount equal to twelve (12) months of Executive's then-current Base Salary (less all applicable deductions) payable in installments in accordance with the then-current generally applicable payroll schedule of the Company commencing on the first regularly scheduled pay date of the Company processed after Executive has executed, delivered to the Company and not revoked the Release; (2) conditioned on Executive's proper and timely election to continue the Company's health insurance benefits under COBRA, or under applicable state law, reimbursement of the additional costs incurred by Executive for continuing such benefits at the same level in which Executive participated prior to the date Executive's employment terminated for the shorter of (a) to twelve (12) months from the date of termination or (b) until the Executive obtains reasonably comparable coverage, with such reimbursements to begin at the same time as severance pay set forth in Section 5(c)(ii)(A).

(d) Resignation as Officer and Director. Upon termination of this Restated Agreement and the Executive's employment hereunder for any reason by either party, the Executive shall be deemed to have resigned from all offices and positions the Executive may hold with the Company at such time including without limitation Board membership and/or positions as an officer of the Company.

6. Proprietary Information Agreement. The terms of the Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement by and between the Company and the Executive, entered into simultaneously herewith (the "**Proprietary Information Agreement**") and any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation between the Company and the Executive, are hereby incorporated by reference and are a material part of this Restated Agreement.

7. Representations and Warranties.

(a) The Executive represents and warrants to the Company that the Executive's performance of this Restated Agreement and as an employee of the Company does not and will not breach any noncompetition agreement or any agreement to keep in confidence proprietary information acquired by the Executive in confidence or in trust prior to the Executive's employment by the Company. The Executive represents and warrants to the Company that the Executive has not entered into, and agrees not to enter into, any agreement that conflicts with or violates this Restated Agreement.

(b) The Executive represents and warrants to the Company that the Executive has not brought and shall not bring with the Executive to the Company, or use in the performance of the Executive's responsibilities for the Company, any materials or documents of a former employer which are not generally available to the public or which did not belong to the Executive prior to the Executive's employment with the Company, unless the Executive has obtained written authorization from the former employer or other owner for their possession and use and provided the Company with a copy thereof.

8. Indemnification.

(a) By the Employee. The Executive shall indemnify and hold harmless the Company, its directors, officers, stockholders, agents, and employees against all claims, costs, expenses, liabilities, and lost profits, including amounts paid in settlement, incurred by any of them as a result of Executive engaging in actions that constitute Cause under Section 5(b)(iv)B, E, F or G of this Restated Agreement or the breach by the Executive of any provision of Section 6 and/or 7 of this Restated Agreement.

(b) By the Company. The Company will indemnify and hold harmless the Executive from any liabilities and expenses arising from Executive's actions as an officer, director or employee of the Company to the fullest extent permitted by law, excepting any unauthorized acts, intentional or illegal conduct which breaches the terms of this or any other agreement or Company policy, including but not limited to the Proprietary Information Agreement.

9. Notices. All notices, requests, consents, approvals, and other communications to, upon, and between the parties shall be in writing and shall be deemed to have been given, delivered, made, and received when: (a) personally delivered; (b) deposited for next day delivery by Federal Express, or other similar overnight courier services; (c) transmitted via telefacsimile or other similar device to the attention of the Company President with receipt acknowledged; or (d) three days after being sent or mailed by certified mail, postage prepaid and return receipt requested, addressed to the Company at 8480 Honeycutt Road, Suite 120, Raleigh, NC 27615, and to the Executive at the address set forth by the signature page below.

10. Effect. This Restated Agreement may be assigned by the Company to its successors in interests. This Restated Agreement shall be binding on and inure to the respective benefit of the Company and its successors and assigns and the Executive and Executive's personal representatives**.**

11. Entire Agreement. This Restated Agreement and the Proprietary Information Agreement and any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation constitute the entire agreement between the parties with respect to the matters set forth herein and supersede all prior agreements and understandings between the parties with respect to the same.

12. Severability. The invalidity or unenforceability of any provision of this Restated Agreement shall not affect the validity or enforceability of any other provision.

13. Amendment and Waiver. A waiver of any breach of this Restated Agreement shall not constitute a waiver of any other provision of this Restated Agreement or any subsequent breach of this Restated Agreement. No provision of this Restated Agreement may be amended, modified, deleted, or waived in any manner except by a written agreement executed by the parties.

14. Section 409A Matters. This Restated Agreement is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended and the Treasury Regulations and other applicable guidance thereunder ("**Section 409A**"). To the extent that there is any ambiguity as to whether this Restated Agreement (or any of its provisions) contravenes one or more requirements of Section 409A, such provision shall be interpreted and applied in a matter that does not result in a Section 409A violation. Without limiting the generality of the above:

(a) For clarity, the severance benefits specified in this Restated Agreement (the "**Severance Benefits**") are only payable upon a "separation from service" as defined in Section 409A. The Severance Benefits shall be deemed to be series of separate payments, with each installment being treated as a separate payment. The time and form of payment of any compensation may not be deferred or accelerated to the extent it would result in an impermissible acceleration or deferral under Section 409A.

(b) To the extent this Restated Agreement contains payments which are subject to Section 409A (as opposed to exempt from Section 409A), the Executive's rights to such payments are not subject to anticipation, alienation, sale, transfer, pledge, encumbrance, attachment or garnishment and, where applicable, may only be transferred by will or the laws of descent and distribution.

(c) To the extent the Severance Benefits are intended to be exempt from Section 409A as a result of an "involuntary separation from service" under Section 409A, if all conditions necessary to establish the Executive's entitlement to such Severance Benefits have been satisfied, all Severance Benefits shall be paid or provided in full no later than December 31st of the second calendar year following the calendar year in which the Executive's employment terminated unless another time period is applicable.

(d) If the Employee is a "specified employee" (as defined in Section 409A) on the termination date and a delayed payment is required by Section 409A to avoid a prohibited distribution under Section 409A, then no Severance Benefits that constitute "non-qualified deferred compensation" under Section 409A shall be paid until the earlier of (i) the first day of the 7th month following the date of Employee's "separation from service" as defined in Section 409A, or (ii) the date of Employee's death. Upon the expiration of the applicable deferral period, all payments deferred under this clause shall be paid in a lump sum and any remaining severance benefits shall be paid per the schedule specified in this Restated Agreement.

(e) The Company makes no representation that this Restated Agreement will be exempt from or compliant with Section 409A and makes no affirmative undertaking to preclude Section 409A from applying, but does reserve the right to unilaterally amend this Restated Agreement as may be necessary or advisable to permit the Agreement to be in documentary and operational compliance with Section 409A which determination will be made in the sole discretion of the Company.

15. Governing Law. This Restated Agreement shall be construed, interpreted, and governed in accordance with and by North Carolina law and the applicable provisions of federal law ("Applicable Federal Law"). Any and all claims, controversies, and causes of action arising out of or relating to this Restated Agreement, whether sounding in contract, tort, or statute, shall be governed by the laws of the state of North Carolina, including its statutes of limitations, except for Applicable Federal Law, without giving effect to any North Carolina conflict-of-laws rule that would result in the application of the laws of a different jurisdiction. Both Executive and the Company acknowledge and agree that the state or federal courts located in North Carolina have personal jurisdiction over them and over any dispute arising under this Restated Agreement, and both Executive and the Company irrevocably consent to the jurisdiction of such courts.

16. Consent to Jurisdiction and Venue. Each of the parties agrees that any suit, action, or proceeding arising out of this Restated Agreement may be instituted against it in the state or federal courts located in Wake County, North Carolina. Each of the parties hereby waives any objection that it may have to the venue of any such suit, action, or proceeding, and each of the parties hereby irrevocably consents to the personal jurisdiction of any such court in any such suit, action, or proceeding.

17. Counterparts. This Restated Agreement may be executed in more than one counterpart, each of which shall be deemed an original, and all of which shall be deemed a single agreement**.**

18. Headings. The headings herein are for convenience only and shall not affect the interpretation of this Restated Agreement.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Restated Agreement as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Sandeep Laumas, MD
Name: Sandeep Laumas, MD
Title: Executive Chair, Board of Directors

CHRISTOPHER P. PRIOR, PH.D.

/s/ Christoper P. Prior, Ph.D.

Address:

AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This Amended and Restated Employment Agreement ("Restated Agreement") is executed on the 11th day of March, 2018 (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Jay P. Madan (the "**Executive**"). The Executive and the Company may be referred to herein as a "**Party**" or collectively as the "**Parties**."

W I T N E S S E T H:

Executive has been employed by privately held Innovate Biopharmaceuticals Inc. ("**Private Innovate**") in the role of the President of the Company subject to the terms of an Executive Employment Agreement, dated October 28, 2015, as amended on February 26, 2016, March 1, 2017, and August 31, 2017 (collectively the "**Prior Agreement**").

On January 29, 2018, Monster Digital, Inc. ("**Monster**"), and Private Innovate completed a reverse recapitalization in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated July 3, 2017 (the "**Merger Agreement**"), by and among Monster, Monster Merger Sub, Inc. ("**Merger Sub**") and Private Innovate, which changed its name in connection with the transaction to IB Pharmaceuticals Inc. ("**IB Pharmaceuticals**"). Pursuant to the Merger Agreement, Merger Sub merged with and into IB Pharmaceuticals with IB Pharmaceuticals surviving as the wholly owned subsidiary of Monster (the "**Merger**"). Immediately following the Merger, Monster changed its name to the Company.

Both Executive and the Company wish to continue the employment relationship on the updated terms set forth in this Restated Agreement, which provide Executive with greater benefits than those under his Prior Agreement. This Restated Agreement is intended to replace and supersede the Prior Employment Agreement.

In consideration of the foregoing, of the mutual promises herein, and of other good and valuable consideration, including the continued employment of the Executive by the Company and the compensation to be received by the Executive from the Company from time to time, and specifically the compensation to be received by the Executive pursuant to Section 4 hereof, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending legally to be bound, hereby agree as follows:

1. Employment. As of the Effective Date, the Company hereby continues to employ the Executive and the Executive hereby accepts employment as the President and Chief Business Officer ("**CBO**") of the Company upon the terms and conditions of this Restated Agreement. The Executive shall report to the Chief Executive Officer ("**CEO**") of the Company. As of the Effective Date, the parties agree that the Prior Agreement between the Parties shall terminate.

2. Duties.

(a) The Executive shall faithfully perform all duties of the Company related to the position or positions held by the Executive, including but not limited to all duties set forth in this Restated Agreement and/or in the Bylaws of the Company related to the position or positions held by the Executive and all additional duties that are prescribed from time to time by the Board. The Executive shall devote the Executive's full time and attention to the performance of the Executive's duties and responsibilities on behalf of the Company and in furtherance of its best interests; provided, however, that the Executive, subject to the Executive's obligations hereunder, shall also be permitted to make personal investments, perform reasonable volunteer services and, with the written prior consent of the Company, serve on outside boards of directors for non-profit or for profit corporations. The Executive shall comply with all written Company policies, standards, rules and regulations (the "**Company Policies**") and all applicable government laws, rules and regulations that are now or hereafter in effect. The Executive acknowledges receipt of copies of all written Company Policies that are in effect as of the date of this Restated Agreement.

(b) Executive's base of operation shall be Raleigh, North Carolina, subject to reasonable business travel.

3. Term. The term of this Restated Agreement shall continue until terminated by either party as set forth in Section 5 of this Restated Agreement (the "**Term**").

4. Compensation. During the Term, as compensation for the services rendered by the Executive under this Restated Agreement, the Executive shall be entitled to receive the following (all payments are subject to applicable withholdings):

(a) Base Salary. Executive shall be paid an annual salary in the amount of $285,000 (less applicable withholdings), to be retroactively effective as of March 1, 2018, which shall be payable in accordance with the then-current payroll schedule of the Company (the "**Base Salary**"). The Executive's salary will be reviewed periodically and may be increased from time to time by the Company at its discretion.

(b) Bonuses. Executive shall be eligible to participate in any bonus or similar incentive plan adopted by the Company as approved by the Board of Directors ("**Board**") for executives at Executive's level. The amount awarded, if any, to the Executive under any bonus or incentive plan shall be in the discretion of the Board or any committee administering such plan. Executive's bonus, if any, shall be subject to the terms and conditions of any plan or program adopted or approved by the Board.

(c) Equity. Executive shall be eligible to participate in any equity compensation plan or similar program adopted by the Company when approved by the Board and, if applicable, the Company's shareholders, for executives at Executive's level. The amount awarded, if any, to the Executive under any such plan shall be in the discretion of the Board or any committee administering such plan and shall be subject to the terms and conditions of any plan or program adopted or approved by the Board.

(d) Benefits. The Executive shall be entitled to receive those benefits provided from time to time to other executive employees of the Company, in accordance with the terms and conditions of the applicable plan documents; provided that the Executive meets the eligibility requirements thereof. All such benefits are subject to amendment or termination from time to time by the Company without the consent of the Executive or any other employee of the Company.

(e) Paid Time Off. The Executive shall be entitled to four weeks of paid time off ("**PTO**") to be taken in accordance with the Company's standard PTO policies.

(f) Business Expenses. The Company will reimburse Executive for reasonable travel, entertainment, and other expenses incurred by Executive in the furtherance of the performance of Executive's duties hereunder, in accordance with the Company's expense reimbursement policy for senior executives as in effect from time to time. Provided, however, that the Company will make the reimbursement only if the corresponding expense is incurred during the term of this Restated Agreement and the reimbursement is made on or before the last day of the calendar year following the calendar year in which the expense is incurred, the amount of expenses eligible for such reimbursement during a calendar year will not affect the amount of expenses eligible for such reimbursement in another calendar year, and the right to such reimbursement is not subject to liquidation or exchange for another benefit from the Company.

5. Termination. This Restated Agreement and the Executive's employment by the Company shall or may be terminated, as the case may be, as follows:

(a) Termination by the Executive. The Executive may terminate this Restated Agreement and Executive's employment by the Company:

(i) for "Good Reason" (as defined herein). For purposes of this Restated Agreement, "**Good Reason**" shall mean, the existence, without the consent of the Executive, of any of the following events: (A) the Executive's duties and responsibilities are substantially reduced or diminished; (B) the Executive's base salary is reduced by more than 15% from the level prior to such reduction, except for an across the board reduction in base salary for all executive officers (C) the Company materially breaches its obligations under this Restated Agreement; or (D) the Executive's place of employment is relocated by more than 50 miles. In addition to any requirements set forth above, in order for any of the above events to constitute "Good Reason", the Executive must (X) inform the Company of the existence of the event within 90 days of the initial existence of the event, after which date the Company shall have no less than 30 days to cure the event which otherwise would constitute "Good Reason" hereunder and (Y) the Executive must terminate employment with the Company for such "Good Reason" no later than two years after the initial existence of the event which prompted the Executive's termination.

(ii) Other than for Good Reason 30 days after notice to the Company.

(b) Termination by the Company. The Company may terminate this Restated Agreement and the Executive's employment by the Company upon notice to the Executive (or personal representative):

(i) at any time and for any reason;

(ii) upon the death of the Executive, in which case this Restated Agreement shall terminate immediately; provided that, such termination shall not prejudice any benefits payable to the Executive's spouse or beneficiaries which are fully vested as of the date of death;

(iii) if the Executive is “permanently disabled” (as defined herein), in which case this Restated Agreement shall terminate immediately; provided that, such termination shall not prejudice any benefits payable to the Executive, the Executive’s spouse or beneficiaries which are fully vested as of the date of the termination of this Restated Agreement. For purposes of this Restated Agreement, the Executive shall be considered “**permanently disabled**” when a qualified medical doctor mutually acceptable to the Company and the Executive or the Executive’s personal representative shall have certified in writing that: (A) the Executive is unable, because of a medically determinable physical or mental disability, to perform substantially all of the Executive’s duties, with or without a reasonable accommodation, for more than 180 calendar days measured from the last full day of work; or (B) by reason of mental or physical disability, it is unlikely that the Executive will be able, within 180 calendar days, to resume substantially all business duties and responsibilities in which the Executive was previously engaged and otherwise discharge the Executive’s duties under this Restated Agreement; or

(iv) "for cause" (as defined herein). “**For cause**” shall be determined by the Company and shall mean:

A. Any material breach of the terms of this Restated Agreement by the Executive, or the material failure of the Executive to diligently perform the Executive’s duties for the Company or the Executive’s material failure to achieve her objectives specified by the Board; provided, however, that the Company must first provide Executive with written notice of the grounds under this Section 5(b)(iv)(A) and a period of ten (10) business days in which to cure such grounds;

B. The Executive’s unauthorized use of the Company’s tangible or intangible property (excluding incidental use) or Executive’s breach of the Proprietary Information Agreement (as defined herein) or any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation;

C. Any material failure to comply with material Company Policies, applicable government laws, rules and regulations and/or directives of the Board;

D. The Executive’s use of illegal drugs or any illegal substance, or the Executive’s use of alcohol in any manner that materially interferes with the performance of the Executive’s duties under this Restated Agreement;

E. Any dishonest or illegal action (including, without limitation, embezzlement) or any other action whether or not dishonest or illegal by the Executive which is materially detrimental to the interest and well-being of the Company, including, without limitation, harm to its reputation;

F. The Executive’s failure to fully disclose any material conflict of interest that the Executive may have with the Company in a transaction between the Company and any third party which is materially detrimental to the interest and well-being of the Company; or

G. Any adverse action or omission by the Executive which would be required to be disclosed pursuant to public securities laws or which would limit the ability of the Company or any entity affiliated with the Company to sell securities under any Federal or state law or which would disqualify the Company or any affiliated entity from any exemption otherwise available to it.

(c) Obligations of the Company Upon Termination.

(i) Upon the termination of this Restated Agreement: (A) by the Executive pursuant to paragraph 5(a)(ii); or (B) by the Company pursuant to paragraph 5(b)(ii), (iii), or (iv) the Company shall have no further obligations hereunder other than the payment of all compensation and other benefits payable to the Executive through the date of such termination which shall be paid on or before the Company's next regularly scheduled payday unless such amount is not then-calculable, in which case payment shall be made on the first regularly scheduled payday after the amount is calculable.

(ii) Upon termination of this Restated Agreement: (A) by the Executive pursuant to paragraph 5(a)(i); or (B) by the Company pursuant to paragraph 5(b)(i) and provided that the Executive first executes and does not revoke a release and settlement agreement in the form acceptable to the Company within the time period then-specified by the Company but in any event no later than sixty (60) days after the date of termination (the "**Release**"): (1) the Company shall pay the Executive an amount equal to twelve (12) months of Executive's then-current Base Salary (less all applicable deductions) payable in installments in accordance with the then-current generally applicable payroll schedule of the Company commencing on the first regularly scheduled pay date of the Company processed after Executive has executed, delivered to the Company and not revoked the Release; (2) conditioned on Executive's proper and timely election to continue the Company's health insurance benefits under COBRA, or under applicable state law, reimbursement of the additional costs incurred by Executive for continuing such benefits at the same level in which Executive participated prior to the date Executive's employment terminated for the shorter of (a) to twelve (12) months from the date of termination or (b) until the Executive obtains reasonably comparable coverage, with such reimbursements to begin at the same time as severance pay set forth in Section 5(c)(ii)(A).

(d) Resignation as Officer and Director. Upon termination of this Restated Agreement and the Executive's employment hereunder for any reason by either party, the Executive shall be deemed to have resigned from all offices and positions the Executive may hold with the Company at such time including without limitation Board membership and/or positions as an officer of the Company.

6. Proprietary Information Agreement. The terms of the Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement by and between the Company and the Executive, entered into simultaneously herewith (the "**Proprietary Information Agreement**") and any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation between the Company and the Executive, are hereby incorporated by reference and are a material part of this Restated Agreement.

7. Representations and Warranties.

(a) The Executive represents and warrants to the Company that the Executive's performance of this Restated Agreement and as an employee of the Company does not and will not breach any noncompetition agreement or any agreement to keep in confidence proprietary information acquired by the Executive in confidence or in trust prior to the Executive's employment by the Company. The Executive represents and warrants to the Company that the Executive has not entered into, and agrees not to enter into, any agreement that conflicts with or violates this Restated Agreement.

(b) The Executive represents and warrants to the Company that the Executive has not brought and shall not bring with the Executive to the Company, or use in the performance of the Executive's responsibilities for the Company, any materials or documents of a former employer which are not generally available to the public or which did not belong to the Executive prior to the Executive's employment with the Company, unless the Executive has obtained written authorization from the former employer or other owner for their possession and use and provided the Company with a copy thereof.

8. Indemnification.

(a) By the Employee. The Executive shall indemnify and hold harmless the Company, its directors, officers, stockholders, agents, and employees against all claims, costs, expenses, liabilities, and lost profits, including amounts paid in settlement, incurred by any of them as a result of Executive engaging in actions that constitute Cause under Section 5(b)(iv)B, E, F or G of this Restated Agreement or the breach by the Executive of any provision of Section 6 and/or 7 of this Restated Agreement.

(b) By the Company. The Company will indemnify and hold harmless the Executive from any liabilities and expenses arising from Executive's actions as an officer, director or employee of the Company to the fullest extent permitted by law, excepting any unauthorized acts, intentional or illegal conduct which breaches the terms of this or any other agreement or Company policy, including but not limited to the Proprietary Information Agreement.

9. Notices. All notices, requests, consents, approvals, and other communications to, upon, and between the parties shall be in writing and shall be deemed to have been given, delivered, made, and received when: (a) personally delivered; (b) deposited for next day delivery by Federal Express, or other similar overnight courier services; (c) transmitted via telefacsimile or other similar device to the attention of the Company President with receipt acknowledged; or (d) three days after being sent or mailed by certified mail, postage prepaid and return receipt requested, addressed to the Company at 8480 Honeycutt Road, Suite 120, Raleigh, NC 27615, and to the Executive at the address set forth by the signature page below.

10. Effect. This Restated Agreement may be assigned by the Company to its successors in interests. This Restated Agreement shall be binding on and inure to the respective benefit of the Company and its successors and assigns and the Executive and Executive's personal representatives**.**

11. Entire Agreement. This Restated Agreement and the Proprietary Information Agreement and any other similar agreement regarding confidentiality, intellectual property rights, non-competition or non-solicitation constitute the entire agreement between the parties with respect to the matters set forth herein and supersede all prior agreements and understandings between the parties with respect to the same.

12. Severability. The invalidity or unenforceability of any provision of this Restated Agreement shall not affect the validity or enforceability of any other provision.

13. Amendment and Waiver. A waiver of any breach of this Restated Agreement shall not constitute a waiver of any other provision of this Restated Agreement or any subsequent breach of this Restated Agreement. No provision of this Restated Agreement may be amended, modified, deleted, or waived in any manner except by a written agreement executed by the parties.

14. Section 409A Matters. This Restated Agreement is intended to comply with the requirements of Section 409A of the Internal Revenue Code of 1986, as amended and the Treasury Regulations and other applicable guidance thereunder ("**Section 409A**"). To the extent that there is any ambiguity as to whether this Restated Agreement (or any of its provisions) contravenes one or more requirements of Section 409A, such provision shall be interpreted and applied in a matter that does not result in a Section 409A violation. Without limiting the generality of the above:

(a) For clarity, the severance benefits specified in this Restated Agreement (the "**Severance Benefits**") are only payable upon a "separation from service" as defined in Section 409A. The Severance Benefits shall be deemed to be series of separate payments, with each installment being treated as a separate payment. The time and form of payment of any compensation may not be deferred or accelerated to the extent it would result in an impermissible acceleration or deferral under Section 409A.

(b) To the extent this Restated Agreement contains payments which are subject to Section 409A (as opposed to exempt from Section 409A), the Executive's rights to such payments are not subject to anticipation, alienation, sale, transfer, pledge, encumbrance, attachment or garnishment and, where applicable, may only be transferred by will or the laws of descent and distribution.

(c) To the extent the Severance Benefits are intended to be exempt from Section 409A as a result of an "involuntary separation from service" under Section 409A, if all conditions necessary to establish the Executive's entitlement to such Severance Benefits have been satisfied, all Severance Benefits shall be paid or provided in full no later than December 31st of the second calendar year following the calendar year in which the Executive's employment terminated unless another time period is applicable.

(d) If the Employee is a "specified employee" (as defined in Section 409A) on the termination date and a delayed payment is required by Section 409A to avoid a prohibited distribution under Section 409A, then no Severance Benefits that constitute "non-qualified deferred compensation" under Section 409A shall be paid until the earlier of (i) the first day of the 7th month following the date of Employee's "separation from service" as defined in Section 409A, or (ii) the date of Employee's death. Upon the expiration of the applicable deferral period, all payments deferred under this clause shall be paid in a lump sum and any remaining severance benefits shall be paid per the schedule specified in this Restated Agreement.

(e) The Company makes no representation that this Restated Agreement will be exempt from or compliant with Section 409A and makes no affirmative undertaking to preclude Section 409A from applying, but does reserve the right to unilaterally amend this Restated Agreement as may be necessary or advisable to permit the Agreement to be in documentary and operational compliance with Section 409A which determination will be made in the sole discretion of the Company.

15. Governing Law. This Restated Agreement shall be construed, interpreted, and governed in accordance with and by North Carolina law and the applicable provisions of federal law ("Applicable Federal Law"). Any and all claims, controversies, and causes of action arising out of or relating to this Restated Agreement, whether sounding in contract, tort, or statute, shall be governed by the laws of the state of North Carolina, including its statutes of limitations, except for Applicable Federal Law, without giving effect to any North Carolina conflict-of-laws rule that would result in the application of the laws of a different jurisdiction. Both Executive and the Company acknowledge and agree that the state or federal courts located in North Carolina have personal jurisdiction over them and over any dispute arising under this Restated Agreement, and both Executive and the Company irrevocably consent to the jurisdiction of such courts.

16. Consent to Jurisdiction and Venue. Each of the parties agrees that any suit, action, or proceeding arising out of this Restated Agreement may be instituted against it in the state or federal courts located in Wake County, North Carolina. Each of the parties hereby waives any objection that it may have to the venue of any such suit, action, or proceeding, and each of the parties hereby irrevocably consents to the personal jurisdiction of any such court in any such suit, action, or proceeding.

17. Counterparts. This Restated Agreement may be executed in more than one counterpart, each of which shall be deemed an original, and all of which shall be deemed a single agreement**.**

18. Headings. The headings herein are for convenience only and shall not affect the interpretation of this Restated Agreement.

[The remainder of this page is intentionally left blank.]

IN WITNESS WHEREOF, the parties have executed this Restated Agreement as of the day and year first above written.

COMPANY:

INNOVATE BIOPHARMACEUTICALS, INC.

By: /s/ Christopher P. Prior, Ph.D.
Name: Christopher P. Prior, Ph.D.
Title: Chief Executive Officer

JAY P. MADAN

/s/ Jay P. Madan

Address:

Exhibit 21.1

SUBSIDIARIES OF INNOVATE BIOPHARMACEUTICALS, INC.

Company Name	Jurisdiction
IB Pharmaceuticals Inc.	Delaware

Exhibit 23.1

Consent of Independent Registered

Public Accounting Firm

We consent to the incorporation by reference in the registration statement on Form S-8 (File No. 333-215406) of our report, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern, dated March 12, 2018, on our audits of the consolidated financial statements of Monster Digital, Inc. and Subsidiaries as of December 31, 2017 and 2016 and for the years then ended, included in this Annual Report on Form 10-K of Innovate Biopharmaceuticals, Inc. (formerly Monster Digital, Inc.) for the year ended December 31, 2017.

/s/ CohnReznick LLP

Roseland, New Jersey
March 12, 2018

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Christopher Prior, certify that:

1. I have reviewed this annual report on Form 10-K of Innovate Biopharmaceuticals, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Christopher Prior

March 13, 2018

Christopher Prior
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Jay Madan, certify that:

1. I have reviewed this annual report on Form 10-K of Innovate Biopharmaceuticals, Inc. (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 13, 2018

By: /s/ Jay Madan
Jay Madan
President, Chief Business Officer and Interim Principal Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

I, Christopher Prior, Chief Executive Officer of Innovate Biopharmaceuticals, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Annual Report on Form 10-K of the Company for the year ended December 31, 2017 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: March 13, 2018

/s/ Christopher Prior
Christopher Prior
Chief Executive Officer
(Principal Executive Officer)

This certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

I, Jay Madan, President, Chief Business Officer and Interim Principal Financial Officer of Innovate Biopharmaceuticals, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

(1) the Annual Report on Form 10-K of the Company for the year ended December 31, 2017 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: March 13, 2018

/s/ Jay Madan
Jay Madan
President, Chief Business Officer and Interim Principal Financial Officer
(Principal Financial Officer)

This certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.