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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019
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	Trading Symbol	Name of each exchange on which registered
Common Stock $0.0001 Par Value	INNT	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 ☑

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 ☑

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 ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes ☑ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☑	Smaller reporting company	☑
		Emerging growth company	☑

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. ☑

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

The aggregate value of common stock held by non-affiliates of the registrant as of June 28, 2019, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $39.5 million (based on the last reported closing sale price on the Nasdaq Capital Market on that date of $1.16 per share).

As of March 17, 2020, the registrant had 41,324,976 shares of common stock, par value $0.0001 per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains 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," "might," "could," "will," "estimate," "continue," "anticipate," "intend," "target," "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 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; our proposed merger with RDD Pharma, Ltd. and acquisition of Naia Rare Diseases, Inc.; 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; the impact of COVID-19; and other risks described with these in greater detail in the "Risk Factors" section 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.

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PART I

Item 1. Business.

History of the Company

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 "Monster Merger Agreement"), by and among Monster, Monster Merger Sub, Inc. ("Monster Merger Sub") and Private Innovate, which changed its name in connection with the transaction to IB Pharmaceuticals Inc. ("IB Pharmaceuticals"). Pursuant to the Monster Merger Agreement, Monster Merger Sub merged with and into IB Pharmaceuticals with IB Pharmaceuticals surviving as the wholly owned subsidiary of Monster (the "Monster Merger"). Immediately following the Monster Merger, Monster changed its name to Innovate Biopharmaceuticals, Inc. ("Innovate" or "the Company"). In connection with the closing of the Monster Merger, Innovate's common stock began trading on the Nasdaq Capital Market under the ticker symbol "INNT" on February 1, 2018. Prior to the Monster 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 Monster Merger on January 29, 2018 and, where applicable, the business of Private Innovate prior to the Monster Merger. All references to "Monster" refer to Monster Digital, Inc. prior to the closing of the Monster Merger.

On October 7, 2019, the Company announced that it had entered into an Agreement and Plan of Merger and Reorganization, dated October 6, 2019 (the "RDD Merger Agreement"), pursuant to which the Company agreed to acquire all of the outstanding capital stock of privately held RDD Pharma, Ltd. ("RDD"), an Israel corporation, in exchange for a combination of common and preferred shares to be issued by the Company to the existing RDD shareholders (the "RDD Merger"). The RDD Merger includes a concurrent capital raise led by OrbiMed Advisors LLC, with a minimum funding requirement of $10 million (the "RDD Merger Financing"). Following completion of the RDD Merger and RDD Merger Financing, on an as-converted, fully diluted basis, the current Innovate stockholders will own approximately 62% of the combined company's capital stock and the current RDD stockholders will own approximately 38% of the combined company's capital stock. The final ownership percentages are subject to dilution based on the final amount of capital invested in the RDD Merger Financing, which will dilute both the current Innovate stockholders and RDD stockholders on a pro rata basis. Promptly following the effective time of the RDD Merger, expected to close near the end of the first quarter of 2020. However, the COVID-19 pandemic may affect access to capital and could impact the timing of the Company's proposed merger with RDD. The Company intends to file an amendment to its certificate of incorporation to change its name from Innovate Biopharmaceuticals, Inc. to 9 Meters Biopharma, Inc. The closing of the RDD Merger is subject to customary closing conditions. For more information about RDD and the RDD Merger, see our proxy solicitation materials filed with the U.S. Securities and Exchange Commission ("SEC") on January 22, 2020.

Overview - Innovate

We are a clinical-stage biopharmaceutical company developing novel medicines for autoimmune and inflammatory diseases with unmet medical needs. Our pipeline includes drug candidates for celiac disease, nonalcoholic steatohepatitis (NASH), and ulcerative colitis (UC). Our lead program, INN-202 (larazotide acetate or larazotide) is currently in Phase 3 registration trials for celiac disease, an unmet medical need, and we currently anticipate top-line results in 2021. We are the first company to enter a phase 3 trial for celiac disease. INN-202 has the potential to be the first-to-market therapeutic for celiac disease, 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" labeled foods, which contains enough gluten 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. We continue to monitor the evolving situation with the novel coronavirus (COVID-19), which is likely to directly or indirectly impact the pace of enrollment over the next several months as patients may avoid or may be restricted from traveling to healthcare facilities and physician's offices unless due to a health urgency.

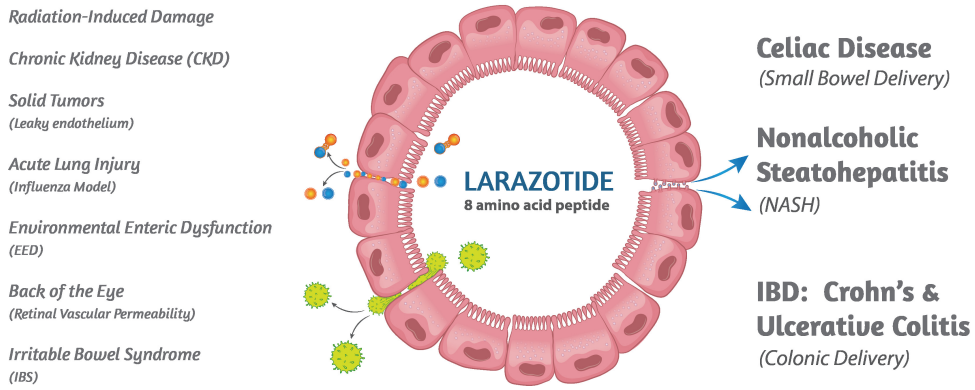

Figure 1: Larazotide's mechanism of action is applicable to multiple diseases.

Larazotide is an 8-amino acid peptide formulated into an orally administered capsule and has been tested in nearly 600 celiac patients with statistically significant improvement in celiac symptoms. The FDA has granted larazotide Fast Track Designation for celiac disease. Larazotide's safety profile has been similar to placebo. Additionally, larazotide's mechanism of action as a tight junction regulator is a new approach to treating autoimmune diseases, such as celiac disease. Multiple 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 mechanism of action. Increased intestinal permeability underlies several diseases in addition to celiac disease, including NASH, ASH, Crohn's disease, ulcerative colitis and irritable bowel syndrome-diarrhea predominant (IBS-D), 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.

Celiac Disease (CeD)

With the release of the Phase 2b trial data in 342 celiac patients at the 2014 Digestive Disease Week 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 patient reported outcome primary end point for celiac disease created specifically for celiac disease and wholly owned by us ("CeD PRO"). After a successful End-of-Phase 2 meeting with the FDA, which confirmed the regulatory path forward, we launched the Phase 3 registration program in 2019 and dosed the first patient in August 2019, with top-line data expected in 2021. We currently have approximately 100 active sites and have been enrolling patients. Site activation and patient enrollment have been impacted by the announcement of the RDD Merger and the winter holiday season. We continue to monitor the evolving situation with COVID-19, which is likely to directly or indirectly impact the pace of enrollment over the next several months. We currently anticipate a top-line readout for the trial in 2021.

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).

Ulcerative Colitis (UC)

INN-108 is in development for the treatment of 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 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 13) 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. We received Orphan Drug Designation for pediatric usage of INN-108 from the FDA in 2017.

Non-alcoholic Steatohepatitis (NASH)

Larazotide is also being tested as a therapy for NASH in pre-clinical models. NASH is an unmet disease affecting approximately 5%-6% of the U.S. adult population. There are several drugs in development for NASH; however, to our knowledge, none have larazotide's mechanism of action. We are developing a proprietary formulation of larazotide, INN-217, for efficient delivery to the large intestine. INN-217 has the potential to reduce the transport of lipopolysaccharide (LPS), which is produced by gram negative bacteria in the gut and translocated from the intestinal lumen to the liver via the portal circulation.

Magnetic Resonance Cholangiopancreatography (MRCP)

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. INN-329 has Orphan Drug Designation for usage in MRCP.

Overview - RDD Pharma, Ltd.

RDD is a privately held specialty pharmaceutical company focused on development and commercialization of orphan and innovative therapies for gastrointestinal ("GI") disorders. RDD has exclusively developed drug candidates that are new therapeutic entities based on known or approved molecules with established safety and toxicology profiles. By choosing medications that are already approved for other indications and combining them with a proprietary drug-delivery technology, RDD benefits from a short regulatory route while maintaining patent protection.

RDD has three clinical-stage products which serve significant unmet needs in the anorectal region. RDD's pipeline includes drug candidates for fecal incontinence in patients with spinal cord injury (RDD-0315), pruritis ani (RDD-1609), and radiation colitis (RDD-2007). RDD recently completed a successful Phase 2a study in Europe of RDD-0315 in fecal incontinence, which reached the primary endpoint (lowered frequency of incontinence events). Additionally, RDD-0315 has received Orphan Drug status in the E.U. and Fast Track designation in the U.S. There are no approved therapies for this indication. RDD received institutional review board ("IRB") approval for Phase 2a clinical trials for RDD-1609 and expects to complete the study in the second half of 2020.

On November 12, 2019, RDD entered into a nonbinding letter of intent with Naia Rare Diseases ("Naia"), a privately held biopharmaceutical company developing drugs for short bowel syndrome ("SBS") and other rare GI diseases, to acquire all of the outstanding capital stock of Naia in exchange for a combination of cash and shares of the combined company, as well as certain earn-out payments (the "Naia Acquisition"). Closing of the Naia Acquisition is anticipated to occur shortly after the consummation of the RDD Merger but is not guaranteed. In exchange, it is anticipated that Naia will receive a combination of cash and shares in the combined company, subject to closing of the RDD Merger. However, the Naia Acquisition is not a condition to close the RDD Merger.

Through the transaction, the combined company would acquire Naia's investigational therapeutic, NB-1001, a long-acting glucagon-like peptide-1 ("GLP-1") receptor agonist that combines exenatide with a proprietary extended half-life technology for treatment of SBS. Long-acting NB-1001 extends the half-life of GLP-1 and allows for up to once-per-month dosing, considerably increasing administration convenience with a potentially improved safety profile versus other GLP-1 agonists secondary to lower overall exposure and dose required. The proposed agreement includes a glucagon-like peptide 2 ("GLP-2") analogue with improved serum half-life compared with short-acting versions, which RDD intends to progress through a clinical and regulatory pathway in an undisclosed orphan and rare GI indication.

NB-1001 has demonstrated efficacy and an extended half-life up to 30 days in a 70-patient clinical study and received orphan drug designation by the U.S. Food and Drug Administration. The companies, along with Cedars-Sinai Medical Center, plan to initiate a clinical program in SBS in 2020, with the goal of developing a safer, more efficacious and convenient therapy.

RDD Pharma Ltd. was founded in Israel in 2008. RDD has two wholly-owned subsidiaries, RDD Pharma Limited, founded in England in 2015, and RDD Pharma Inc., founded in Delaware in 2013.

Innovate's Strategy

Our goal is to become a leading biopharmaceutical company focused on autoimmune and inflammatory disorders 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 the Phase 3 clinical trial for INN-202 (larazotide) for celiac disease.*** Our highest clinical priority is to complete the Phase 3 trials for larazotide for the treatment of celiac disease which began in 2019. We had a successful End-of-Phase 2 meeting with the FDA in 2017. We plan to announce top-line results in 2021. We have approximately 100 active clinical trial sites with three treatment groups, 0.25 mg of larazotide, 0.5 mg of larazotide and a placebo arm. As discussed above, we continue to monitor the evolving situation with COVID-19, which could directly or indirectly impact the pace of enrollment over the next several months. We currently anticipate a top-line readout for the trial in 2021.
- ***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 or 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. We have initiated research collaborations with Dr. O. Colin Stine of the University of Maryland at Baltimore to study larazotide's corrective effect on the dysfunctional intestinal barrier and the dysfunctional microbiome in various diseases and a research collaboration with Dr. James Nataro of the University of Virginia, Charlottesville, to study larazotide's effect on Environmental Enteric Dysfunction.
- ***Seek partnerships to commercialize late stage pipeline drugs.*** With large addressable markets, such as celiac disease, UC and NASH, 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, grounded in securing composition of matter patents and method of use patents for new indications. We plan to develop new formulations for the current product candidates for other indications and improve performance of existing product 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 and to facilitate the rapid development of our pipeline by using high quality specialist vendors and consultants in a capital efficient manner.

Innovate's 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):

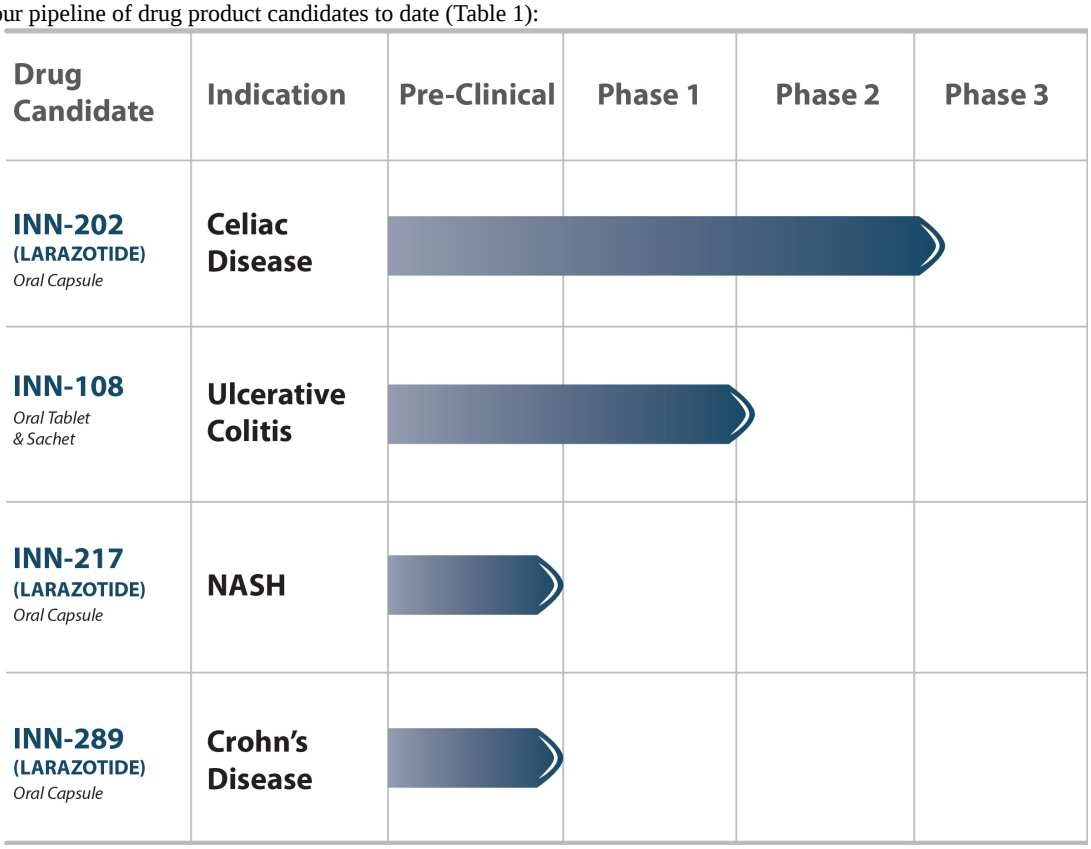

Table 1: Our key pipeline products are clinical stage and address large markets with chronically dosed therapies.

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 launched the Phase 3 trials for celiac disease in 2019 and expect to announce top-line results in 2021.

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. Because of larazotide's lack of absorption into the blood circulation, we believe that fewer complications, if any, are likely to develop for individuals taking 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.

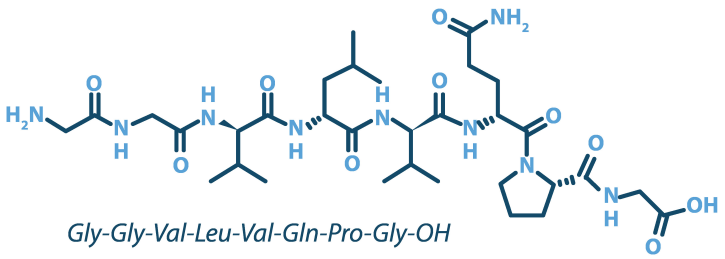

Figure 3: Larazotide acetate is an 8-amino acid peptide in an oral capsule using a proprietary formulation

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 leaky 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 while 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.

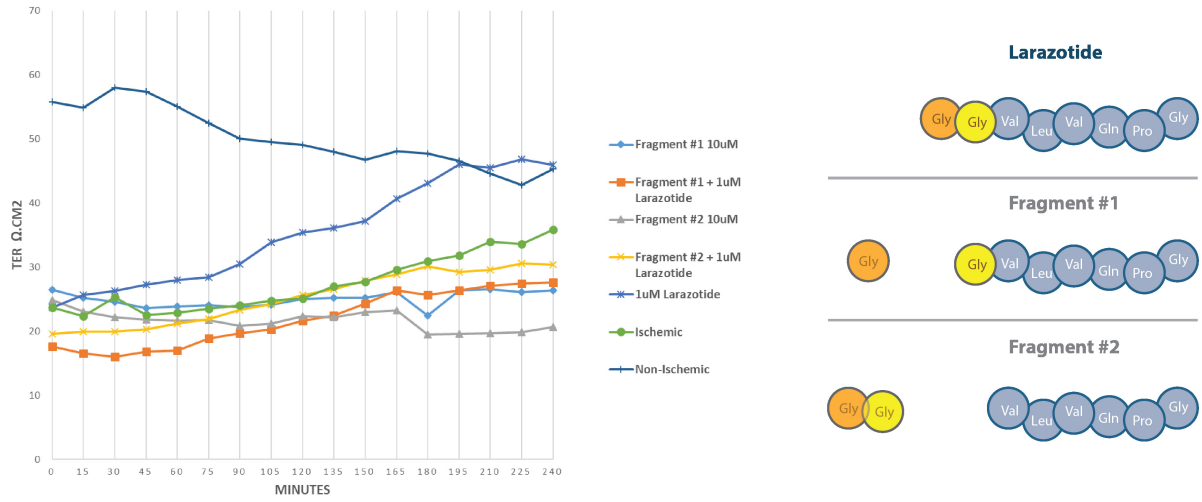

Figure 4: An aminopeptidase in the brush border cleaves larazotide into two fragments; fragment #2 acts as an inhibitor of larazotide

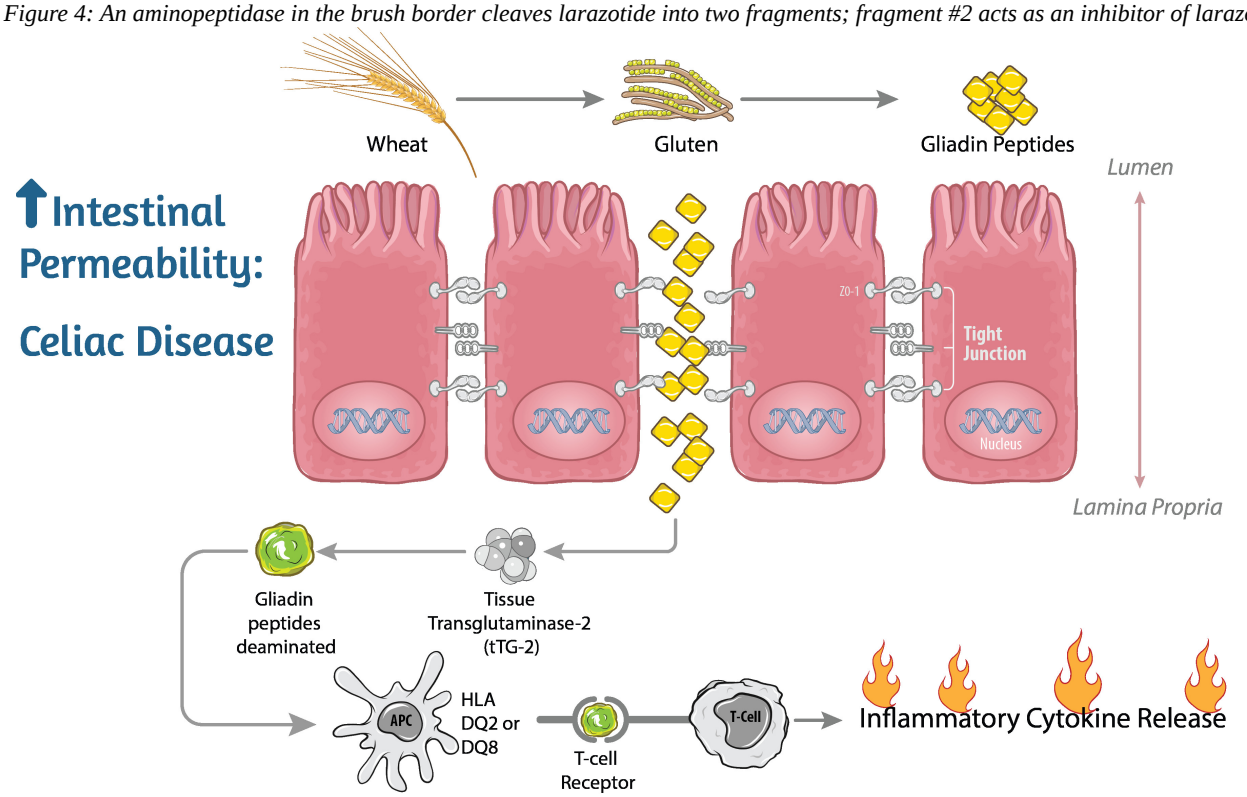

Figure 5: Illustrative effect of gluten ingestion. Breakdown to gliadin peptides which can cross a "leaky" epithelial barrier in the small bowel thus activating the intestinal-inflammatory loop and leading to symptoms and villous atrophy.

As we further instigate larazotide's dose response, we are also exploring larazotide analogs and derivatives by which we may be able to offer a longer acting molecule with a traditional dose response to improve efficacy. A molecule that would be resistant to proteolytic degradation. We continue to work with our academic collaborators to further investigate.

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 GI 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 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 nearly 600 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. During the course of the seven clinical studies, 5 patients experienced a serious adverse event, of which 2 received placebo and 3 received larazotide. These events included inflammation of the gallbladder, gall stones, depression, allergic reaction to penicillin and appendicitis. We do not believe that any 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 the 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). Subjects remained on their gluten-free diets throughout the duration of the trial except for nine hundred (900) mg of gluten that was taken with each meal. 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 CeD 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 GI symptoms in subjects with celiac disease undergoing a gluten challenge.

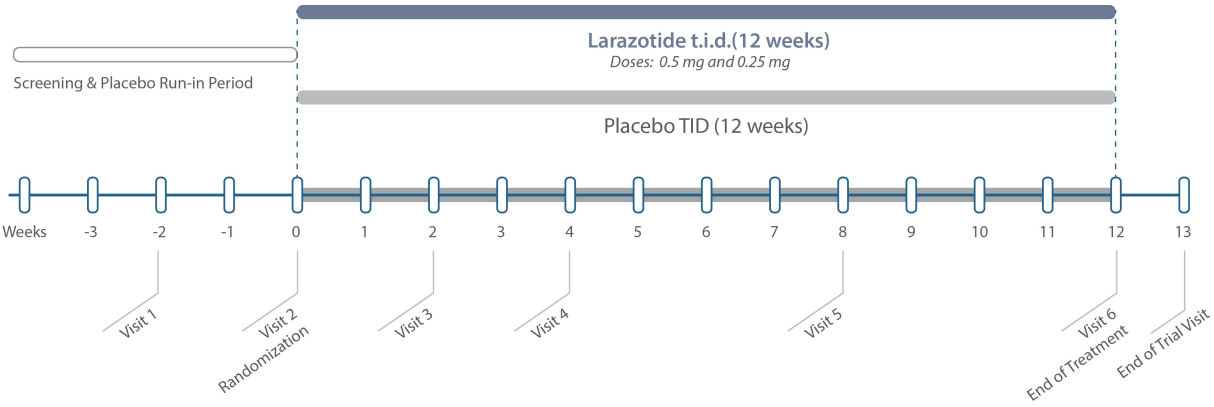

Figure 6: The overall trial designs for Phase 2b and Phase 3 are similar with a screening period followed by 12 weeks of randomization to larazotide vs. placebo.

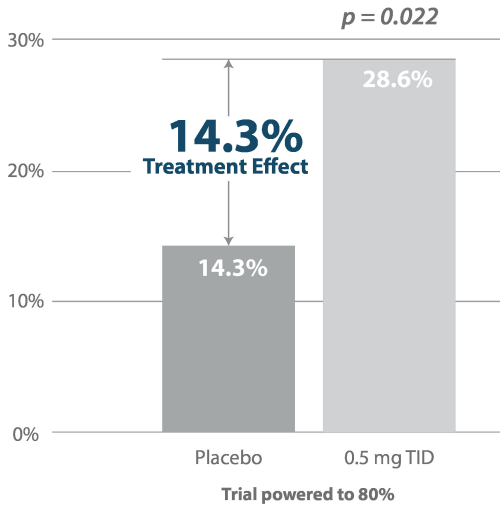

Figure 7: Responder Rate Analysis: Larazotide is the only drug in development for celiac disease to meet its primary endpoint with statistical significance (shown above) as measured by CeD GSRS and the copyrighted CeD PRO, an FDA-agreed upon primary endpoint for Phase 3. Source: Gastroenterology 2015; 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 was administered TID, 15 minutes prior to each meal. After a screening period, subjects were asked to continue following their current gluten-free diets 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 (CeD-PRO), weekly symptoms (CeD GSRS), bowel movements (BSFS) and a self-reported daily general well-being assessment.

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 mg and 2 mg TID) or placebo, suggesting a narrow dose range around the 0.5 mg dose, which also seems to correlate with pre-clinical data.

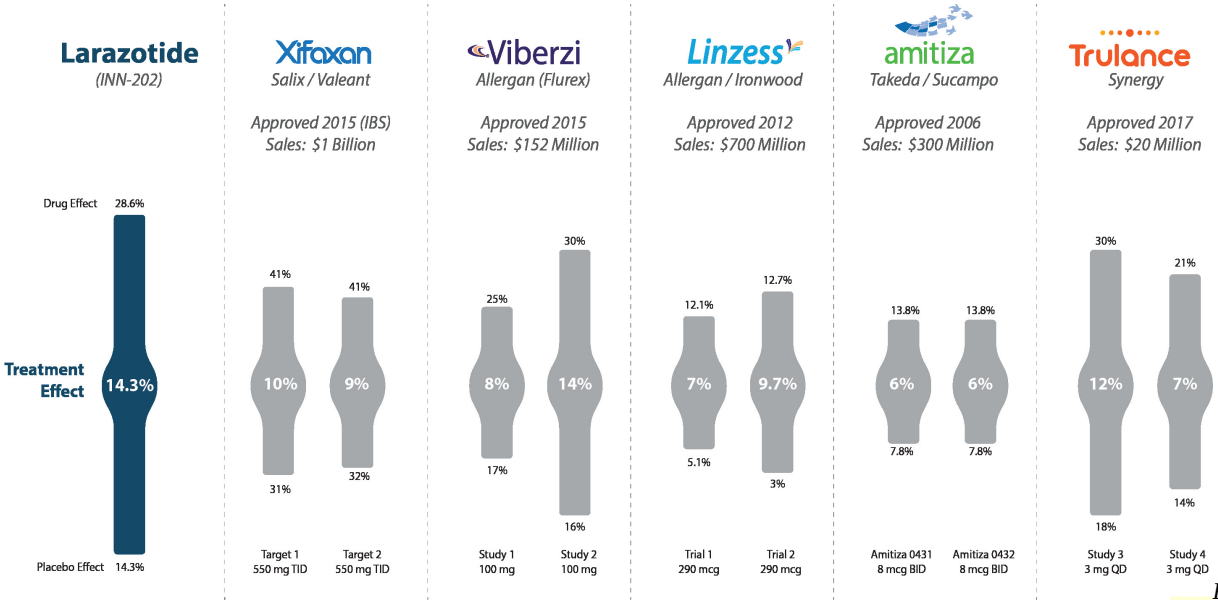

Figure 8: Treatment effect of larazotide from the Phase 2b trial ('012) compared to approved IBS/CIC drugs with varying treatment effects mostly in the mid to high single digit range. Source: Gastroenterology 2015; 148:1311–1319; p. 1315 and FDA Drug Labels

The CeD PRO 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).

Phase 3 Clinical Trial Design

After an End-of-Phase 2 meeting with the FDA, agreements were reached on the key aspects of the Phase 3 clinical 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 approximately 600 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, remained similar to the '012 Phase 2b trial.

We have approximately 100 active clinical trial sites with three treatment groups, 0.25 mg of larazotide, 0.5 mg of larazotide and a placebo arm. We continue to monitor the evolving situation with COVID-19, which is likely to directly or indirectly impact the pace of enrollment over the next several months. We currently anticipate a top-line readout for the trial in 2021.

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 ''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.

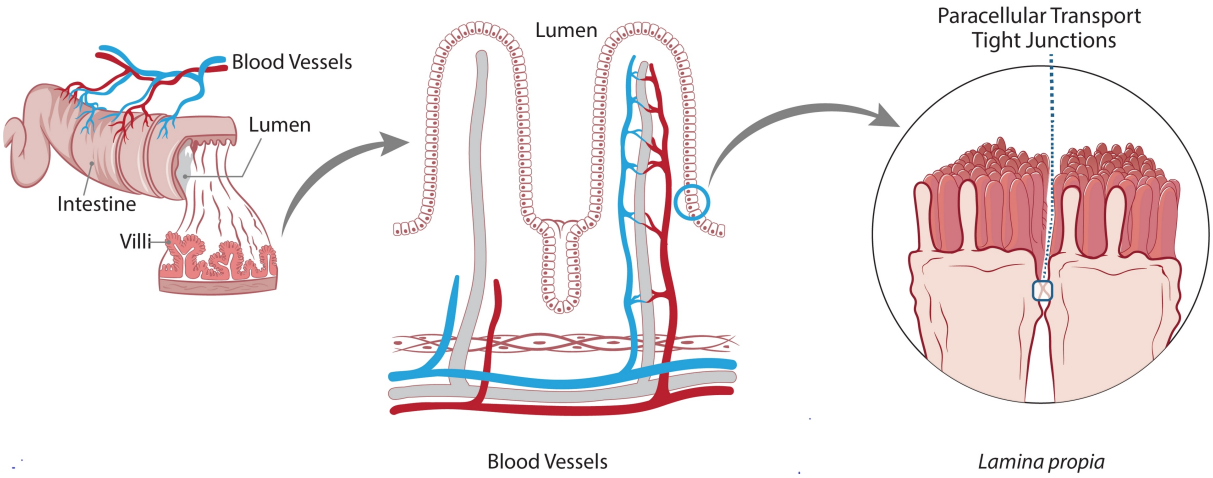

Figure 9: The epithelial barrier separates the intestinal content from the immune system (lamina propria) and the vasculature.

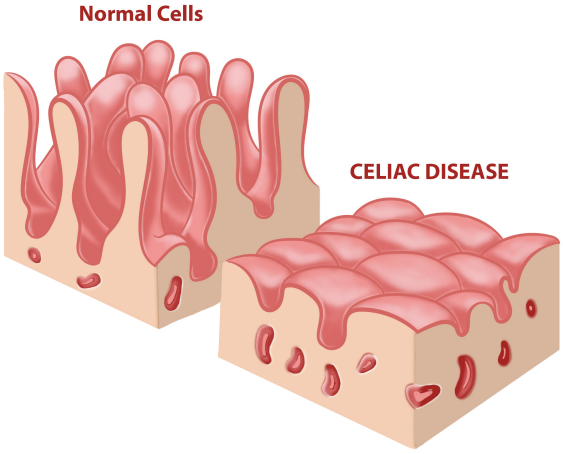

Figure 10: Intestinal villi atrophy in celiac patients, a characteristic finding upon biopsy of the small intestine.

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 diagnosed with 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.

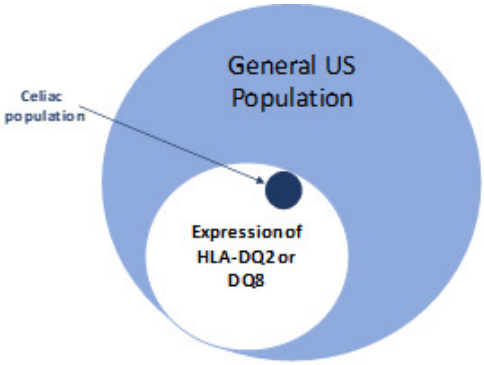

Figure 11: Distribution of HLA-DQ2/DQ8 in the general US population and in celiac disease. Source: J. Clin. Invest. 2007 Jan 2;117(1):41.

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.

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 GI 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 GI 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 and up to 500 mg/day of gluten exposure. Due to the presence of gluten in foods, beer, liquor, cosmetics and household products, exposure is difficult to completely avoid and due to cross-contamination, celiac patients have increased risks of exposure to gluten, which can cause symptoms more frequently.

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 60% (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. The only treatment for achieving and maintaining permanent control of DH is a strict lifelong adherence to a gluten-free diet. It appears in approximately 25% of patients with celiac disease of all ages, however mainly in adults and is a characteristic clinical presenting symptom.

INN-108: Ulcerative Colitis

INN-108 is in development for UC and previously completed phase 1 trials in the treatment of mild-to-moderate UC. We may enter a proof-of-concept Phase 2 trial, subject to receipt of additional financing. 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 remains 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 Bausch/Salix's Apriso (approved 2008).

The initial IND was filed with the FDA by Nobex Corporation on May 15, 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 March 19, 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 a mechanism of action 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.

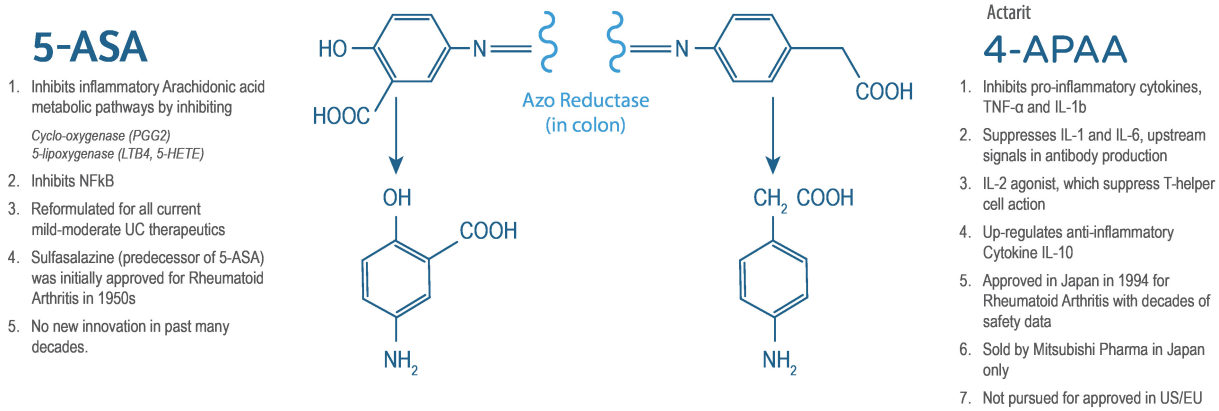

Figure 13: 4-APAA is covalently bonded to 5-ASA via a high energy azo-bond which is only enzymatically cleaved in the colon. The anti-inflammatory effect of each of 5-ASA and 4-APAA via different pathways which could lead to a potential synergistic anti-inflammatory effect as seen in animal studies.

INN-108 Clinical Development Pathway

After completing two Phase 1 studies, the first of which was conducted in 2003, and the second of which was conducted in 2004, a profile was established with dosing of mesalamine and 4-APAA at 2 grams each for a total of 4 grams three times a day.

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. Subject to future funding or a change in the treatment landscape for UC, we would plan to compare INN-108 to mesalamine seeking to demonstrate a greater clinical effect than mesalamine alone.

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.

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

NASH is a growing epidemic affecting approximately 5% to 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.

INN-217, a new class of medicine based on gut-restricted peptides which re-normalize the intestinal epithelial barrier and gut-liver axis, is the first drug with this novel mechanism to show improvements in validated NASH biomarkers and endpoints. Key top-line findings from a biopsy-proven translational mouse model of NASH (the AMLN-diet Gubra NASH mouse model). In a 12-week preclinical study of larazotide acetate combined with OCA, data demonstrated statistically significant reductions in plasma total cholesterol ($p<0.001$), absolute ($p<0.05$) and relative liver weights ($p<0.01$), relative ($p<0.001$) and total liver cholesterol ($p<0.001$), and relative ($p<0.01$) and absolute liver triglycerides ($p<0.001$), when compared to vehicle control animals that did not receive any larazotide or OCA. The NAS score improved in the majority of animals treated with the combination of larazotide and OCA when compared to vehicle ($p<0.001$). Histological steatosis scores trended positively, and lobular inflammation was statistically significantly improved ($p<0.01$) in the larazotide and OCA group when compared to vehicle control animals.

According to a marketing and research firm, GlobalData, the market for NASH therapeutics is expected to grow significantly. GlobalData estimates that the market in the United States, France, Germany, Italy, Spain, the United Kingdom and Japan for such therapeutics will be approximately $25.3 billion by 2026. We expect that this market could be addressed by INN-217, however we are unable to estimate what portion until the effect of larazotide in this population has been studied in clinical trials to better understand the specific patient-type in NASH that may derive benefit. We only intend to advance development of INN-217 through partnerships, collaborations or other strategic relationships.

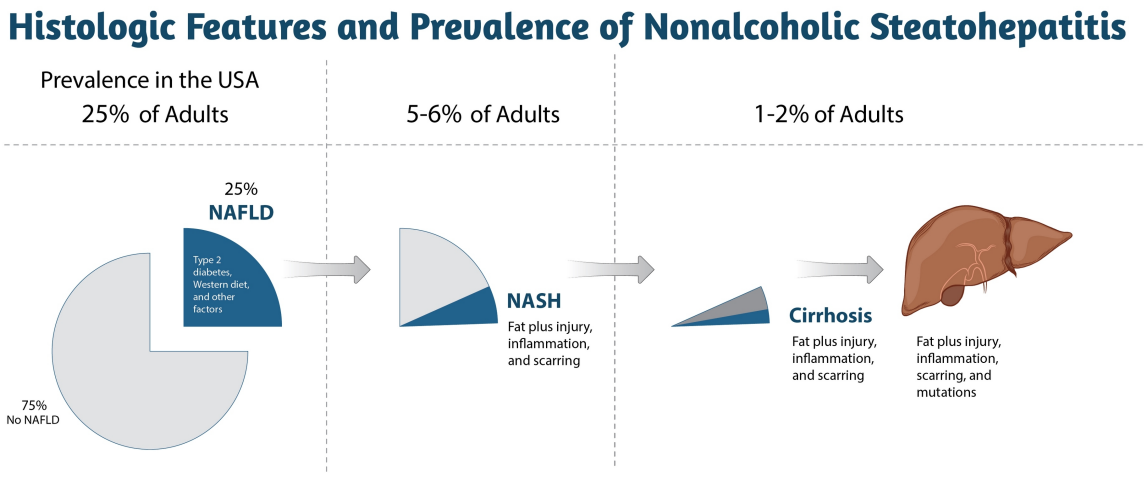

Figure 12: Growing NASH population up to 5%-6% of adults in the US alone.

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-329: Magnetic Resonance Cholangiopancreatography

INN-329 is 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. 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.

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 24 U.S. patents and 106 foreign patents with expiration dates ranging from 2021 to 2031. 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 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, we believe 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 us, 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. During 2019, we paid Alba a milestone payment of $0.3 million for the dosing of the first patient in our Phase 3 clinical trial. If we 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 foreign patents covering the composition-of-matter for the larazotide peptide expired in 2019. 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.

Significant patents in the INN-202 patent estate include issued patents in the U.S. for methods of treating celiac disease with larazotide, (US Patents 8,034,776 and 9,279,807), of which the last to expire has a term to July 16, 2030. The INN-202 patent estate also includes provisional patent applications for pharmaceutical compositions, delivery compositions, and methods of treatment. These patent applications have not yet been issued, so the expiration dates of any intellectual property that might result from these applications are unknown.

Other significant patents include the larazotide formulation patent family, which has three issued U.S. patents as well as 46 issued outside the U.S. The significant patents in the INN-202 patent estate formulation patent family includes patents covering the composition-of-matter (US Patent 9,265,811) and corresponding methods of treatment (US Patents 8,168,594 and 9,241,969) for the larazotide formulation, with the last to expire patent having an expiration in the U.S. of June 4, 2031.

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% 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 August 29, 2021 (in the U.S.) and March 22, 2025 (in Europe);

(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 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; therefore, 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 between five and fifteen of annual net sales, with such 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 INN-108 in the markets of the United States, France, Germany, Italy, Spain, the United Kingdom and Japan. We have exclusive rights in all global markets for INN-202, other larazotide programs and INN-329. We plan to pursue regulatory approvals for our products in the United States and the European Union. We may independently commercialize these products in the United States and other markets and 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 research and development 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, including Takeda/PvP's KumaMax (gluten degrading enzyme), Takeda's TAK-101, Amgen/Provention Bio'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, yet an NIH sponsored trial is evaluating a patient subset in a phase 2 trial launched in March 2019. ImmunosanT discontinued their Phase 2b trial for their Nexvax2 vaccine due to lack of statistically meaningful protection from gluten exposure for celiac disease patients when compared with placebo.

Product	Status	Mechanism	Company	Route	Product Type
AMG 714	Phase 2	Anti-IL-15 MAb	Amgen/ Provention Bio	Subcutaneous; 2x/month	MAb (humanized)
TAK-101	Phase 1	Nanoparticle containing gliadin	Takeda/Cour Pharmaceuticals	IV	Gliadin peptides
ZED-1227	Phase 1b	TGase-2 inhibitor	Zedira GmbH/ Dr Falk Pharma	Oral	Small molecule (peptidomimetic)
KumaMax	Phase 1	Enzymatic degradation of gluten	Takeda/PvP Biologics	Oral	Recombinant enzyme
IMGX003	Phase 2	Two gluten degrading enzymes	ImmunogenX	Oral	Recombinant enzymes

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.

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 and efficacy 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 an 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 ("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 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, pharmacokinetics and pharmacodynamics. In the case of some products for severe or life-threatening diseases, the initial human testing may be 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.

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 (for example, long term carcinogenicity 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 an 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 an 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 an 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 has been granted approval designation, 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 an 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 an 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 an 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 and will issue a Complete Response Letter.

The testing and approval process require 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 an 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. The Approval Letter may contain Post-Marketing Requirements (PMRs) or Post-Marketing Commitments (PMCs) which comprise studies or clinical trials that the Sponsor is required or has committed to conducting. 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 an 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.

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

Innovate had research and development expenses of $13.7 million and $7.6 million for the years ended December 31, 2019 and 2018, respectively.

Employees

We currently have eight full-time employees and 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, Monster 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 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 (this exemption was recently extended indefinitely for smaller reporting companies, as defined in Rule 12b-2 of the Exchange Act, with revenue of less than $100 million);
- 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 accompanying 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

Our ability to raise capital in the future may be limited by applicable laws and regulations.

On March 15, 2018, we filed a shelf registration statement on Form S-3 that was declared effective on July 13, 2018 registering shares of our common stock for issuance in primary offerings. Using a shelf registration statement on Form S-3 to raise additional capital generally takes less time and is less expensive than other means, such as conducting an offering under a Form S-1 registration statement. However, our ability to raise capital using a shelf registration statement may be limited by, among other things, SEC rules and regulations. Under SEC rules and regulations, if our public float (the market value of our common stock held by non-affiliates) is less than $75.0 million, at the time we update our Form S-3 as required under Section 10(a)(3) of the Securities Act, then as of the time of such update until our public float again exceeds $75.0 million, the aggregate market value of securities sold by us or on our behalf under our Form S-3 in any 12-month period will be limited to an aggregate of one-third of our public float. We expect that we will become subject to this limitation with the filing of our Annual Report on Form 10-K for the year ended December 31, 2019. If our ability to utilize a Form S-3 registration statement for a primary offering of our securities is limited to one-third of our public float or precluded altogether due to failure to satisfy other eligibility requirements of such Form, we may conduct such an offering pursuant to an exemption from registration under the Securities Act or under a Form S-1 registration statement, and we would expect either of those alternatives to increase the cost of raising additional capital relative to utilizing a Form S-3 registration statement.

In addition, under current SEC rules and regulations, our common stock must be listed and registered on a national securities exchange in order to utilize a Form S-3 registration statement (i) for a primary offering, if our public float is not at least $75.0 million as of a date within 60 days prior to the date of filing the Form S-3 or a re-evaluation date, whichever is later, and (ii) to register the resale of our securities by persons other than us (i.e., a resale offering). While currently our common stock is listed on the Nasdaq Capital Market, there can be no assurance that we will be able to maintain such listing.

Our ability to timely raise sufficient additional capital also may be limited by Nasdaq's stockholder approval requirements for transactions involving the issuance of our common stock or securities convertible into our common stock. For instance, Nasdaq requires that we obtain stockholder approval of any transaction involving the sale, issuance or potential issuance by us of our common stock (or securities convertible into our common stock) at a price less than the lower of the closing price immediately preceding the signing of the binding agreement for the offering and the average closing price for the five trading days immediately preceding the signing of the binding agreement for the offering, which (together with sales by our officers, directors and principal stockholders) equals 20% or more of our then outstanding common stock, unless the transaction is considered a "public offering" by Nasdaq. In addition, certain prior sales by us may be aggregated with any offering we may propose in the future, further limiting the amount we could raise in any future offering without stockholder approval. Nasdaq also requires that we obtain stockholder approval if the issuance or potential issuance of additional shares will be considered by Nasdaq to result in a change of control of the Company.

Obtaining stockholder approval is a costly and time-consuming process. If we are required to obtain stockholder approval for a potential transaction, we would expect to spend substantial additional money and resources. In addition, seeking stockholder approval would delay our receipt of otherwise available capital or alter the terms of the transaction, which may materially and adversely affect our ability to execute our business strategy, and there is no guarantee our stockholders ultimately would approve a proposed transaction.

If we fail to meet the requirements for continued listing on the Nasdaq Capital Market, our common stock could be delisted from trading, which would decrease the liquidity of our common stock and our ability to raise additional capital.

Although our common stock is currently listed on the Nasdaq Capital Market, an active trading market for our shares may not be sustained. We are required to meet specified requirements to maintain our listing on the Nasdaq Capital Market, including, among other things, a minimum $35 million market value of listed securities and a minimum bid price of $1.00 per share. On December 4, 2019, we received notice from the staff of the Nasdaq Stock Market LLC, (the "Staff") notifying us that for the last 30 consecutive business days, the bid price for our common stock had closed below the minimum $1.00 per share requirement for continued inclusion on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2). In addition, on December 4, 2019, we received a notice from the Staff notifying us that for the last 30 consecutive business days, the market value of our listed securities had been below the minimum requirement of $35 million for continued inclusion on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(2), and that we also did not meet the alternative requirements for satisfying continued listing criteria. We have been provided a period of 180 calendar days, or until June 1, 2020, to regain compliance with the Nasdaq Listing Rules 5550(a)(2) and 5550(b)(2). If, at any time before June 1, 2020, the bid price of our common stock closes at $1.00 per share or more and/or the market value of our listed securities closes at $35 million or more, in each case for a minimum of ten consecutive business days, the Staff will provide written confirmation to us that we comply with Rule 5550(a)(2) and/or Rule 5550(b)(2), as applicable. If we do not regain compliance with Rule 5550(a)(2) by June 1, 2020, we may be eligible for an additional 180-day compliance period. To qualify, we would be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and would need to provide written notice of our intention to cure the bid price deficiency during the second compliance period, by effecting a reverse stock split, if necessary. After the initial 180-day compliance period, there is no additional compliance period applicable to our noncompliance with Rule 5550(b)(2). If we do not regain compliance with the applicable listing rules when required, the Staff will provide written notification to us that our common stock is subject to delisting. At that time, we may appeal the delisting determination to a Hearings Panel.

We are currently evaluating our options for regaining compliance, including the creation of stockholder value through the execution of business objectives described in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Annual Report on Form 10-K. However, we cannot guarantee that we will regain compliance with the applicable listing requirements by June 1, 2020, or that we will be able to comply with the continued listing standards of the Nasdaq Capital Market, and therefore our common stock may be subject to delisting.

If our common stock is delisted and there is no longer an active trading market for our shares, it may, among other things:

- cause you difficulty in selling your shares without depressing the market price for the shares or selling your shares at all;
- substantially impair our ability to raise additional funds;
- result in a loss of institutional investor interest and fewer financing opportunities for us; and/or
- result in potential breaches of representations or covenants of agreements pursuant to which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations.

A delisting would also reduce the value of our equity compensation plans, which could negatively impact our ability to retain key employees.

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.

We have not been profitable since we commenced operations 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 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, substantial resources have been dedicated to the acquisition and development of our product candidates. We will require significant additional capital to continue operations and to execute on our current business strategy to develop INN-202 through regulatory approval and further develop our other product candidates 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 report on our financial statements for the years ended December 31, 2019 and 2018, included an explanatory paragraph related to recurring losses from operations and our dependence on additional financing to continue as a going concern. We have incurred net losses for the years ended December 31, 2019 and 2018 and had an accumulated deficit of $70.6 million as of December 31, 2019. 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. We intend to continue to finance our operations through debt or equity financings 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 for further development of our product candidates. 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, 2019 and 2018, we incurred losses from operations of $25.5 million and $18.2 million, respectively, and net cash used in operating activities was $18.0 million and $15.2 million, respectively. At December 31, 2019, we had an accumulated deficit of $70.6 million and cash and cash equivalents of $4.6 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 Food and Drug Administration (“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 nonclinical and clinical 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 change 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 strategic alliances or licensing arrangements or other collaborations 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 equity or 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.

The outstanding convertible promissory notes we have issued may be converted into shares of common stock and may also be redeemed in certain circumstances. If the holder of the outstanding convertible promissory notes converts such notes into shares of common stock, our current stockholders could be significantly diluted; if certain events occur and the holder of these notes redeems them, our liquidity and our ability to continue our operations may be materially impaired.

The holder of the unsecured convertible promissory note we issued on March 8, 2019, or the Unsecured Convertible Note, and the additional unsecured convertible promissory note we issued on January 1, 2020, or the Additional Note, can convert all or any portion of such notes, including a premium in some cases, into shares of our common stock at a conversion price that may vary over time. The number of shares of common stock issued upon the conversion of such notes may be significant. The issuance of new shares of common stock upon such conversion will cause the percentage ownership held by each stockholder prior to such issuance to decrease and such decrease in percentage ownership could be significant. We can provide no assurance that the holder of the Unsecured Convertible Note and the Additional Note will not exercise its rights to cause us to repay the notes in cash pursuant to the terms of the notes. If the holder requires us to repay the notes, our ability to continue developing and commercializing our product candidates or operate as a business would be severely restricted.

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 comprehensive tax reform bill passed in 2017 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 federal 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, 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 new 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 the RDD Merger

The RDD Merger is subject to conditions to closing that could result in the RDD Merger being delayed or not consummated, and it can be terminated in certain circumstances, each of which could negatively impact our stock price and future business and operations.

The RDD Merger is subject to conditions to closing as set forth in the RDD Merger Agreement. In addition, we and RDD each have the right, in certain circumstances, to terminate the RDD Merger Agreement. If the RDD Merger Agreement is terminated or any of the conditions to the RDD Merger are not satisfied and, where permissible, not waived, the RDD Merger will not be consummated. Failure to consummate the RDD Merger or any delay in the consummation of the RDD Merger or any uncertainty about the consummation of the RDD Merger may adversely affect our stock price or have an adverse impact on our future business operations.

If the RDD Merger is not completed, our ongoing business may be adversely affected and, without realizing any of the benefits of having completed the RDD Merger, it would be subject to a number of risks, including the following:

- negative reactions from the financial markets and from persons who have or may be considering business dealings with us;
- financial difficulties that we may experience;
- we will be required to pay certain costs relating to the RDD Merger, whether or not the RDD Merger is completed; and
- we have agreed to pay a break-up fee if the RDD Merger Agreement is terminated in certain circumstances.

In addition, we could be subject to litigation related to any failure to complete the RDD Merger or related to any proceeding commenced against us seeking to require us to perform our obligations under the RDD Merger Agreement.

The RDD Merger will present challenges associated with integrating operations, personnel, and other aspects of the companies and assumption of liabilities that may exist at RDD and which may be known or unknown by us.

The results of the combined company following the RDD Merger will depend in part upon our ability to integrate RDD's business with our business in an efficient and effective manner. Our attempt to integrate two companies that have previously operated independently may result in significant challenges, and we may be unable to accomplish the integration smoothly or successfully. In particular, the necessity of coordinating geographically dispersed organizations and addressing possible differences in corporate cultures and management philosophies may increase the difficulties of integration. The integration may require the dedication of significant management resources, which may temporarily distract management's attention from the day-to-day operations of the businesses of the combined company. In addition, the combined company may adjust the way in which RDD or we have conducted our respective operations and utilized our respective assets, which may require retraining and development of new procedures and methodologies. The process of integrating operations and making such adjustments after the RDD Merger could cause an interruption of, or loss of momentum in, the activities of one or more of the combined company's businesses and the loss of key personnel. Employee uncertainty, lack of focus, or turnover during the integration process may also disrupt the businesses of the combined company. Any inability of management to integrate the operations of Innovate and RDD successfully could have a material adverse effect on the business and financial condition of the combined company.

In addition, the RDD Merger will subject us to contractual or other obligations and liabilities of RDD, some of which may be unknown. Although we and our legal and financial advisors have conducted due diligence on RDD and its business, there can be no assurance that we are aware of all obligations and liabilities of RDD. These liabilities, and any additional risks and uncertainties related to RDD's business and to the RDD Merger not currently known to us or that we may currently be aware of, but that prove to be more significant than assessed or estimated by us, could negatively impact the business, financial condition, and results of operations of the combined company following consummation of the RDD Merger.

The pro forma financial statements contained in our proxy statement filed on January 22, 2020 might not be an indication of the combined company's financial condition or results of operations following the RDD Merger.

The pro forma financial statements contained in our proxy statement filed on January 22, 2020 might not be an indication of the combined company's financial condition or results of operations following the RDD Merger for several reasons. For example, the pro forma financial statements have been derived from our historical financial statements and the historical financial statements of RDD and certain adjustments and assumptions have been made regarding the combined company after giving effect to the RDD Merger. The information upon which these adjustments and assumptions have been made is preliminary, and these kinds of adjustments and assumptions are difficult to make with complete accuracy. Moreover, the pro forma financial statements do not reflect all costs that are expected to be incurred by the combined company in connection with the RDD Merger. For example, the impact of any incremental costs incurred in integrating Innovate and RDD is not reflected in the pro forma financial statements. In addition, the assumptions used in preparing the pro forma financial information might not prove to be accurate, and other factors may affect the combined company's financial condition or results of operations following the RDD Merger. Our stock price may be adversely affected if the actual results of the combined company fall short of the pro forma financial statements contained in this proxy statement. See the Unaudited Pro Forma Condensed Combined Financial Statements attached as Annex A to our proxy statement filed on January 22, 2020.

Completion of the RDD Merger would result in the issuance of a significant number of additional shares of our common stock, which would reduce the voting power of our current stockholders and may depress the trading price of our common stock.

Completion of the RDD Merger would result in the issuance of a significant number of shares of our common stock. As a result, our existing stockholders will not exert the same degree of voting power with respect to the combined company that they did before the consummation of the RDD Merger. Further, the issuance of such a significant amount of common stock, and its potential sale in the public market from time to time, could depress the trading price of our common stock and our stockholders may lose all or a part of their investment.

We have incurred and will continue to incur significant transaction, combination-related and restructuring costs in connection with the RDD Merger.

We have incurred and will continue to incur transaction fees and other expenses related to the RDD Merger, including filing fees, legal and accounting fees, soliciting fees, regulatory fees, and printing and mailing costs. We also expect to incur significant costs associated with combining the operations of the two companies. It is difficult to predict the amount of these costs before we begin the integration process. The combined company may incur additional unanticipated costs as a consequence of difficulties arising from efforts to integrate the operations of the two companies. Although we expect that the elimination of duplicative costs, as well as the realization of other efficiencies related to the integration of the businesses, can offset incremental transaction, combination-related, and restructuring costs over time, we may not be able to achieve this net benefit in the near term, or at all. If the RDD Merger is not completed, we would have to recognize these expenses without realizing the expected benefits of the RDD Merger.

Risks Related to RDD's Business

RDD does not have any products that are approved for commercial sale and therefore the combined company will remain subject to many of the same risks regarding the clinical, regulatory and commercial success of these product candidates as we are subject to prior to the closing of the RDD Merger.

RDD currently does not have any therapeutic products approved for commercial sale. Provided that the anticipated RDD Merger closes, the combined company would have ten product candidates at various phases of clinical drug development and will therefore remain subject to the same risks regarding the clinical, regulatory and commercial success of the combined company's product candidates as we are subject to prior to the closing of the RDD Merger. In addition, the combined company will have to determine how best to allocate limited financial resources between the ten therapeutic product candidates, none of which currently generate revenue. The combined company will incur significant costs related to the clinical trials and regulatory approval of our existing therapeutic products, as well as the therapeutic products in RDD's pipeline. The combined company might not receive within the next several years, if at all, any revenues from the commercialization of any of our product candidates, even if a product candidate is approved. Additionally, in the event one or more of our product candidates is approved for commercial sale, the combined company will incur significant costs in connection with commercializing any approved product candidate and the combined company might not generate significant revenue from sales of such products, which would impact our ability to become profitable and maintain profitability.

The combined company might not be able to successfully or timely complete the Naia Acquisition, which could materially impact the market price of the combined company's common stock, financial condition, results of operations and cash flows.

The terms of the Naia Acquisition are subject to further negotiation and the transaction is currently expected to close following the RDD Merger. The Naia Acquisition might not be completed, or might not be completed in the timeframe, on the terms or in the manner currently anticipated. The completion of the Naia Acquisition is subject to further negotiation of a binding agreement. There can be no assurance that the combined company will negotiate the Naia Acquisition on satisfactory terms and enter into a binding agreement, or that other events will not intervene to delay or result in the failure to close the Naia Acquisition. The non-binding letter of intent might be terminated by the parties for any reason prior to the execution of a definitive and binding agreement. If there are delays in negotiating a definitive and binding agreement or delays in closing the transaction, or a failure to close the transaction, the combined company's ongoing business could be materially adversely affected, including without limitation, as follows:

- the combined company might incur significant additional costs in connection with such delay or termination;
- the combined company might experience negative reactions from financial markets and the stock price could decline;
- the combined company might experience negative reactions from employees, suppliers or other third parties; and
- the combined company's management's focus would have been diverted from pursuing other valuable opportunities.

Additionally, if the combined company is unable to consummate the transaction with Naia, the combined company will have incurred significant due diligence, legal, accounting and other transaction costs in connection with the transaction without realizing the anticipated benefits.

If the RDD Merger closes, and we are unable to successfully integrate the RDD and Naia portfolio of products into our existing business operations, or if we do not realize the anticipated benefits of the RDD Merger with RDD or the Naia Acquisition, our business could be adversely affected.

We will need to successfully integrate our business operations with RDD's pipeline of products, which includes drug candidates for fecal incontinence (RDD-0315), pruritis ani (RDD-1609), radiation colitis (RDD-2007) and Naia's pipeline of products, which includes drug candidates for pediatric short bowel syndrome (NB1001) and short bowel syndrome (NB1002). Integrating the RDD and Naia products with our existing business will be a complex and time-consuming process. There might be substantial difficulties, costs and delays involved in any integration of these products. These might include:

- distracting management and key functional areas from day-to-day operations;
- difficulties with respect to the timing and results of ongoing and future clinical trials in the RDD and Naia products; and
- diversion of financial resources that would otherwise be available for the ongoing development or commercialization of our existing programs.

Any one or all of these factors might increase our operating costs and capital needs or lower our anticipated financial performance. Certain of these factors are outside of our control. Achieving the potential benefits underlying our reasons for the merger with RDD will depend on a successful, timely and efficient integration of RDD's pipeline of products.

Even if the integration of RDD's and Naia's portfolios are successful, the RDD Merger might fail to further our business strategy as anticipated or to achieve anticipated benefits and success. We have made assumptions relating to the impact of the RDD and Naia pipelines on our financial results relating to numerous matters, including:

- transaction and integration costs;
- the cost of development and commercialization of RDD's and Naia's products; and
- the other financial and strategic risks related to the RDD Merger.

Further, we might incur higher than expected operating, transaction and integration costs, and we might encounter general economic and business conditions that adversely affect us following the completion of the RDD Merger. If one or more of our assumptions are incorrect, it could have an adverse effect on our business and operating results, and the benefits from the RDD Merger might not be realized or be of the magnitude expected.

Many of RDD's products rely on patent and/or regulatory exclusivity and the combined company's success will depend in part on obtaining and maintaining effective patent and other intellectual property protection for the product candidates and proprietary technology.

As with our current pipeline of products, the products in the RDD product portfolio rely on patent and regulatory exclusivity. The intellectual property rights protecting the RDD products might not afford the combined company with meaningful protection from third parties infringing on the proprietary rights of RDD. Competitors could also design around any of RDD's intellectual property or otherwise design competitive products that do not infringe RDD's intellectual property. If a product is approved for commercial sale and competitors are successful in such designs, it could have an adverse impact on the combined company's revenue or results of operations.

If RDD or the combined company fails to comply with obligations under any license, collaboration or other agreements, the combined company could lose intellectual property rights that are necessary for developing and commercializing product candidates.

RDD's intellectual property relating to the nifedipine capository for anal fissure program is licensed from Mor Research Applications Ltd. RDD's intellectual property relating to the pregabalin for pruritis ani program is licensed from Dr. Eli D. Ehrenpreis. RDD's license agreements with Mor Research Applications Ltd. and Dr. Eli D. Ehrenpreis impose, and any future licenses or collaboration agreements the combined company might enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, patent prosecution and enforcement and other obligations. These type of agreements and related obligations are complex and subject to contractual disputes. If RDD (and the combined company following the closing of the RDD Merger) breach any of these imposed obligations, or use the intellectual property licensed to RDD in an unauthorized manner, RDD (and the combined company following the closing of the RDD Merger) might be required to pay damages or the licensor might have the right to terminate the license, which could result in the loss of the intellectual property rights and RDD (and the combined company following the closing of the RDD Merger) being unable to develop, manufacture and sell drugs that are covered by the licensed technology.

Intense competition might render RDD's GI products noncompetitive or obsolete.

Competition in the GI business is intense and characterized by extensive research efforts and rapid technological progress. Technological developments by competitors, regulatory approval for marketing competitive products, including potential generic or over-the-counter products, or superior marketing resources possessed by competitors could adversely affect the commercial potential of the combined company's GI products and could have a material adverse effect on the combined company's future revenue and results of operations. We believe that there are numerous pharmaceutical and biotechnology companies, as well as academic research groups throughout the world, engaged in research and development efforts with respect to pharmaceutical products targeted at GI diseases and conditions addressed by RDD's product pipeline. In particular, we are aware of products in research or development by competitors that address the diseases being targeted by RDD's products. Developments by others might render RDD's product pipeline obsolete or noncompetitive. Competitors might be able to complete the development and regulatory approval process sooner and, therefore, market their GI products earlier than the combined company can.

Many of RDD's current competitors have significant financial, marketing and personnel resources and development capabilities. For example, many large, well-capitalized companies already offer GI products in the United States and Europe that target the indications for: (i) fecal incontinence including over-the-counter bulking agents such as psyllium or methylcellulose; antidiarrheals such as loperamide, diphenoxylate plus atropine, bismuth subsalicylate or bile acid binders such as cholestyramine; biofeedback involving cognitively retraining pelvic floor and abdominal wall musculature; injectable anal bulking agents such as dextranomer-hyaluronic acid (Solesta®); sacral nerve stimulation and anal sphincteroplasty surgery; (ii) pruritis ani including barrier cream such as those containing zinc oxide in conjunction with or without hydrocortisone cream; antihistamines such as diphenhydramine; topical capsaicin; anal tattooing with intradermal injection of methylene blue; topical formulations containing tacrolimus or other agents involving mechanisms believed to target pruritic mechanisms; (iii) radiation colitis including short chain fatty acid enemas; sucralfate enemas; oral sulfasalazine with or without prednisolone enemas or other mesalamine enemas with or without glucocorticoids; argon plasma coagulation; cryoablation; bipolar electrocoagulation and heater probe; radiofrequency ablation; usage of formalin particularly in colitis with significant bleeding; band ligation; hyperbaric oxygen; hormonal therapy including estrogen with or without progesterone; antioxidants including vitamin E and C; vitamin A or retinoid formulations; stool softeners; metronidazole; pentosan polysulfate; aloe vera; and mesenchymal stem cell therapy; (iv) short bowel syndrome including acid suppressive therapies such as H2 blockers or proton pump inhibitors; antidiarrheals such as loperamide; antibiotics to prevent small intestinal bacterial overgrowth; octrotide for patient with IV fluid requirements greater than 3 L per day; clonidine; GLP-1 analogues including exenatide with or without GLP-2 analogues such

as teduglutide (Gattex®); human growth hormone or somatropin analogues (Zorptive®); bile acid binders such as cholestyramine or pancreatic enzymes to aid in digestion of nutrients.

In addition, other GI products are in research or development by competitors that address the diseases and diagnostic procedures being targeted by RDD's product pipeline.

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. In the event one or more of our product candidates is approved for commercial sale, we will incur significant costs in connection with commercializing any approved product candidate and we may not generate significant revenue from sales of such products, which would impact our ability to become profitable and maintain profitability.

We are substantially dependent upon the clinical, regulatory and commercial success of our product candidates. 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 five product candidates.

The success of our business is primarily dependent on our ability to advance the clinical development of INN-202 for the treatment of celiac disease and INN-108 for the treatment of mild to moderate ulcerative colitis. In addition, we have several other drug product candidates that we may seek to develop through partnerships or other strategic relationships. In the third quarter of 2019, we started the Phase 3 clinical trial for INN-202. Subject to additional financing, we may also prepare for INN-108 to enter 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; and
- 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 chemistry, manufacturing and controls, or 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 European Union, Japan and other markets;
- inability to consistently manufacture commercial supplies of drug and delivery devices resulting in slowed market development and lower revenue;
- inability to enforce our intellectual property rights in and to our product candidates;
- reduction in the safety profile of our product candidates following approval; and
- 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; and
    - poor prescription coverage and inadequate reimbursement for our product candidates.

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.

We have historically operated with a limited number of employees. We currently have eight full-time employees, including one employee engaged full-time and two employees 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.

We may have 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, including those expected to join our management team from RDD if the anticipated RDD Merger closes, 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.

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 company's annual or interim financial statements will not be prevented or detected on a timely basis. Although we are committed to continuing to improve our internal control processes and intend to implement a plan to remediate this material weakness, such implementation will require us to spend limited resources, and 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.

We have historically had limited resources to address our internal controls and procedures and relied on part-time consultants to assist us with our financial accounting and compliance obligations. In connection with the preparation of our audited financial statements for the year ended December 31, 2018, management identified a material weakness existed in internal controls over financial reporting due to inadequate segregation of duties and appropriate level of review. In an effort to remediate this material weakness during the year ended December 31, 2019, we added two full-time finance positions, a Chief Financial Officer who is serving as our Principal Financial Officer and Principal Accounting Officer and a Controller. During the year ended December 31, 2019, we also enhanced our system of internal controls, including improving our segregation of duties. However, management determined that a material weakness in internal control over financial reporting still remains at December 31, 2019.

Our employees, independent contractors and consultants, principal investigators, clinical research organizations ("CROs"), contract manufacturing organizations ("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, 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 Current Good Manufacturing Practices ("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 ethics and business 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 production, 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 Good Clinical Practices (“GCP”), Good Laboratory Practices (“GLP”) and Good Manufacturing Practices (“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.

We currently have eight full-time employees, including one employee engaged full-time and two employees 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.

We or the third parties upon whom we depend may be adversely affected by natural disasters and other catastrophic events, and by man-made problems such as terrorism, that could disrupt our business operations, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters are located in Raleigh, North Carolina, near major hurricane and tornado zones. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged or made unavailable critical infrastructure, such as enterprise financial systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. Our manufacturers' and their suppliers' facilities are located in multiple locations, where other natural disasters or similar events, such as blizzards, tornadoes, fires, explosions or large-scale accidents or power outages, could severely disrupt their operations. In addition, acts of terrorism, pandemic illness and other geo-political unrest could cause disruptions in our business or the businesses of our collaborators, manufacturers or the economy as a whole. All of the aforementioned risks may be further increased if we do not implement a disaster recovery plan or our collaborators' or manufacturers' disaster recovery plans prove to be inadequate. Any of the above could result in delays in the regulatory approval, manufacture, distribution or commercialization of our product candidates.

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and operations.

The recent outbreak of COVID-19 originated in Wuhan, China, in December 2019 and has since spread to multiple countries, including the United States and several European countries. On March 11, 2020, the World Health Organization declared the outbreak a pandemic. The COVID-19 pandemic is affecting the United States and global economies and may affect our operations and those of third parties on which we rely, including by causing disruptions in the supply of our product candidates and the conduct of current and future clinical trials. In addition, the COVID-19 pandemic may affect the operations of the FDA and other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates. The evolving COVID-19 pandemic is also likely to directly or indirectly impact the pace of enrollment in our Phase 3 registration trials for INN-202 for at least the next several months and possibly longer as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency. Such facilities and offices may also be required to focus limited resources on non-clinical trial matters, including treatment of COVID-19 patients, and may not be available, in whole or in part, for clinical trial services related to INN-202 or our other product candidates. Additionally, while the potential economic impact brought by, and the duration of the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity and our and RDD's ability to complete the RDD Merger and RDD Merger Financing on a timely basis or at all. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on our liquidity, capital resources, operations and business and those of the third parties on which we rely.

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, 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.

Use of our proprietary patient-reported outcome measure, CeD PRO, in our Phase 3 clinical trials of larazotide acetate for the treatment of celiac disease may adversely impact our ability to achieve a positive result from these clinical trials.

Patient-reported outcome assessments ("PROs"), involve patients' subjective assessments of efficacy and this subjectivity can increase the uncertainty of clinical trial outcomes. Such assessments can be influenced by a number of factors and can vary widely from day to day for a particular patient, and from patient to patient and site to site within a clinical trial, leading to high variability in PRO measurements.

The variability of PRO measures and high placebo response rates could adversely impact our Phase 3 clinical trials of larazotide acetate for celiac disease. The variability of a PRO measure can complicate clinical trial design, adversely impact the ability of a study to show a statistically significant improvement and generally adversely impact a clinical development program by introducing additional uncertainties.

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.

In 2019, we started the Phase 3 clinical trial for INN-202, larazotide acetate, 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 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. 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, 2018 and 2019, 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, regulations of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use 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 we 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 in lieu of other opportunities 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. We currently intend to focus our limited financial and managerial resources on developing our lead program, INN-202, for the treatment of celiac disease. As a result, we may allocate fewer resources to the other product candidates in our pipeline, and we will be required to seek additional sources of financing to pursue further development of such other product candidates.

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., issued patents outside the U.S. and 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. There are two pending patent applications relating to INN-217 based on Innovate's internal developments.

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* reexamination, 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 the CeD PRO that is protected by copyright until 2106. 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 ("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 their 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 their 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, the U.S. Congress may again attempt to pass reform measures, including the possible repeal and replacement of the Patient Protection and 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 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 in 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 the 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 may provide market exclusivity in the U.S. for seven years 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 may provide market exclusivity in the U.S. for seven years 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.

Obtaining an Orphan Drug Designation from the FDA may not effectively protect our product candidates from competition because different drugs can be approved for the same condition, and orphan drug exclusivity does not prevent the FDA from approving the same or a different drug in another indication. Even after an orphan drug is approved, the FDA can subsequently approve a later application for the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan-drug-exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

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.

Our relationships with investigators, healthcare professionals, institutional providers, consultants, third-party payors and customers are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties, including without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

Healthcare providers, physicians and others play a primary role in the recommendation and prescribing of any product candidates for which we may obtain marketing approval. In the United States, our current business operations and future arrangements with investigators, healthcare professionals, institutional providers, consultants, third-party payors and customers,

may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our products that obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations, include, but are not limited to, the following:

- the federal healthcare program anti-kickback statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, service or item for which payment is made, in whole or in part, under a federal healthcare program;
- the federal civil and criminal false claims laws and civil monetary penalties laws, including civil whistleblower or qui tam actions, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or from knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the omnibus rule, such as health plans, clearinghouses and healthcare providers and their associates;
- HIPAA, imposes criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program regardless of the payor (e.g., public or private) and knowingly or willfully falsifying, concealing, or covering up by any trick, scheme or device a material fact or making any materially false statement in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- the federal transparency law, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), and its implementing regulations, require manufacturers of drugs, devices, biologicals and medical supplies to report to the U.S. Department of Health and Human Services information related to payments and other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous state laws and regulations, including but not limited to: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by state governmental and non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; and state laws and regulations that require manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and
- European Union ("EU"), data protection regulations, which may require member states of the EU to impose minimum restrictions on the collection and use of personal data that, in many respects, are more stringent and impose more significant burdens on subject businesses, than current privacy standards in the United States.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these or any other health regulatory laws or any other governmental regulations that may apply to us, we may be subject to penalties, including without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, enhanced government reporting and oversight under a corporate integrity agreement or other similar arrangement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses or divert our management's attention from the operation of our business. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable healthcare laws, they also may be subject to similar penalties.

Risks Related to Our Common Stock

The market price of our common stock has been and will likely in the future 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 February 1, 2018, through March 17, 2020, the price thereof has ranged from a low of $0.37 per share to a high of $50.50 per share. Companies like us with a lower number of shares comprising their public floats and limited trading activity may experience greater volatility in their stock prices. The market price of our common stock may be highly volatile and could continue to be subject to wide fluctuations in response to various factors. These factors have included or may include the following, some of which are beyond our control:

- 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, or delays in clinical trials for, INN-202 (for celiac disease), INN-108 (for ulcerative colitis) and 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, capital commitments or other transactions;
- 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 competitors;
- changes in financial estimates or guidance, including our ability to meet our future revenue and operating profit or loss estimates or guidance;
- our liquidity position and ability to raise additional capital;
- sales of substantial amounts of our stock by insiders and other 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;
- catastrophic weather and/or global disease pandemics, such as the recent COVID-19; and
- the other factors described in this section entitled "Risk Factors" section.

The stock market in general has recently experienced relatively large price and volume fluctuations, particularly in response to the COVID-19 outbreak. In particular, the market prices of securities of smaller biotechnology and medical device companies have experienced dramatic fluctuations that often have been unrelated or disproportionate to the operating results of these companies. Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. In addition, price volatility may increase if the trading volume of our common stock remains limited or declines.

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 we or our existing stockholders sell, or indicate an intent to sell, substantial amounts of our common stock in the public markets, the trading price of our common stock could decline significantly. On March 15, 2018, we filed a shelf registration statement, or the Shelf Registration Statement, which was declared effective on July 13, 2018. Under the Shelf Registration Statement, we may, from time to time, subject to certain eligibility requirements, sell our common stock in one or more offerings up to an aggregate dollar amount of $175.0 million (of which up to an aggregate of $40 million may be sold in an "at-the-market" offering as defined in Rule 415 of the Securities Act). Effective March 19, 2020, we terminated the ATM facility. In addition, the selling stockholders included in the Shelf Registration Statement may from time to time sell up to an aggregate amount of approximately 13.99 million shares of our common stock (including up to approximately 2.1 million shares issuable upon exercise of warrants) in one or more offerings. As of December 31, 2019, we had 39.5 shares of common stock outstanding and exercisable options and warrants to purchase approximately 14.0 million shares of common stock, excluding out-of-the-money stock options and warrants. In addition, the Unsecured Convertible Note and Additional Note may be converted into shares of our common stock at any time at various conversion prices. On March 18, 2019, we issued short-term warrants to purchase up to 4,181,068 shares of our common stock, or the Short-Term Warrants, and long-term warrants to purchase up to 2,508,634 shares of common stock, or the March Long-Term Warrants. On May 17, 2019, we issued long-term warrants to purchase up to 3,897,010 shares of our common stock, or the New Warrants. Pursuant to a purchase agreement dated April 29, 2019, we issued warrants to purchase up to 4,318,272 shares of our common stock, or the April Warrants, and granted the placement agent warrants to purchase up to 215,914 shares of common stock, or the Placement Agent Warrants. The March Long-Term Warrants, Short-Term Warrants and New Warrants have initial exercise prices equal to $2.56, $4.00 and $2.13 per share, respectively, each subject to certain adjustments. On December 19, 2019, we entered into separate exchange agreements with each of the purchasers of the April Warrants and Placement Agent Warrants, pursuant to which we agreed to issue to the purchasers an aggregate of 5,441,023 shares of our common stock, at a ratio of 1.2 shares for each purchaser warrant in exchange for the cancellation and termination of all of the outstanding April Warrants and Placement Agent Warrants. We filed a registration statement, which was declared effective by the SEC on July 12, 2019, registering the resale of the shares of common stock underlying the March Long-Term Warrants, Short-Term Warrants, New Warrants, April Warrants and Placement Agent Warrants. The Short-Term Warrants and April Warrants were exercisable immediately upon issuance. Therefore, sales of common stock by us or our stockholders under the Shelf Registration Statement or otherwise (including sales pursuant to Rule 144) may represent a significant percentage of our common stock currently outstanding. If we or our stockholders sell, or the market perceives that we or our stockholders intend to sell, substantial amounts of our common stock under the Shelf Registration Statement or otherwise, the market price of our common stock could decline significantly. For example, our closing stock price on July 13, 2018, prior to the Shelf Registration Statement being declared effective, was $23.70 per share, and our closing stock price on July 16, 2018, after the Shelf Registration Statement was declared effective, was $8.08 per share.

The issuance of additional shares of common stock 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 1.9 million shares of our common stock as of December 31, 2019, excluding out-of-the-money stock options and warrants. In addition, the Unsecured Convertible Note and Additional Note may be converted into shares of our common stock at any time at various conversion prices. We also sold 4,181,068 shares of common stock in the March 2019 offering and issued the Short-Term Warrants and March Long-Term Warrants to purchase up to 4,181,068 and 2,508,634 shares of our common stock, respectively, in the concurrent private placement. We also issued New Warrants exercisable for an aggregate of 3,897,010 shares of our common stock. On December 19, 2019, we entered into a separate exchange agreement with each purchaser of the April

Warrants and Placement Agent Warrants, pursuant to which we agreed to issue to the purchasers an aggregate of 5,441,023 shares of our common stock at a ratio of 1.2 shares for each warrant in exchange for the cancellation and termination of all of the outstanding April Warrants and Placement Agent Warrants. The issuance of shares upon exercise of warrants and options or conversion of the Unsecured Convertible Note or Additional Note may result in dilution to the interests of other stockholders and may reduce the trading price of our common stock.

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.

Our efforts to restructure and convert most of our outstanding warrants have diluted and will dilute our existing stockholders, requires significant management resources and may result in little to no incremental capital to our company.

On December 19, 2019, we entered into a separate exchange agreement with each purchaser of the April Warrants and Placement Agent Warrants, pursuant to which we agreed to issue to the purchasers an aggregate of 5,441,023 shares of our common stock at a ratio of 1.2 shares for each warrant in exchange for the cancellation and termination of all of the outstanding April Warrants and Placement Agent Warrants. Effective February 6, 2020, we entered into amendments with the holders of the Short-Term Warrant to extend the exercise period by six months. On February 12, 2020, we offered to amend outstanding warrants to purchase an aggregate of 12,346,631 shares of common stock so as to (i) shorten the exercise period so that they expire concurrently with the closing of the RDD Merger and (ii) reduce the exercise price. All of these transactions have diluted or will dilute our existing stockholders and will continue to require significant management effort to complete. Any capital that we receive will be significantly less than expected under the original warrants and limited by current financial market conditions.

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 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 third party brings a claim against us and/or any of our officers or directors, whether successful or not, a claim for indemnification brought by any of our directors or officers would reduce the amount of funds available for use in our business.

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 21.6% of our outstanding common stock as of December 31, 2019. 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.

Anti-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 the Company, even if a change in control was considered favorable by the stockholders. For example, our board of directors (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 for a classified Board
- 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;
- prohibit director removal without cause and only allow removal with cause, and only allow amendment of certain provisions of our amended and restated certificate of incorporation and our bylaws by the vote of the holders of at least two-thirds of all then-outstanding shares of our common stock;
- grant the Board the exclusive authority to increase or decrease the size of the Board;
- 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.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our officers, directors, employees or agents.

Our bylaws provide that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of fiduciary duty owed by, or other wrongdoing by, any director, officer, employee or agent of the Company to us or our stockholders, creditors or other constituents, (iii) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, our certificate of incorporation or our bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws or (v) any action asserting a claim governed by the internal affairs doctrine; in each case, subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein; provided that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. These choice of forum provisions do not preclude or contract the scope of exclusive federal or concurrent jurisdiction for any actions brought under the Securities Act or the Exchange Act. Accordingly, our choice of forum provisions will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees or agents, which may discourage lawsuits against us and our directors, officers and other employees or agents.

If a court were to find the choice of forum provision contained in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our

business, results of operations, and financial condition. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

We may be subject to litigation related to our status as a public company, 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 related litigation, including class action litigation. We may be the target of this type of litigation, or other litigation related to our status as a public company, in the future. For example, a claim has been filed against us in the Superior Court of the State of Delaware by one of our former consultants who received compensatory stock options, demanding damages of up to approximately $3.6 million plus punitive damages in connection with a delay in his ability and timing to exercise his options and sell the underlying shares of our common stock related to past consulting services. 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 the Board 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.

We will continue to seek additional funds through equity offerings, debt financings, or other capital sources, which may impose restrictions on our business.

In order to raise additional funds to support our operations, we will continue to seek additional funds through equity offerings, debt financings or other capital sources, which may impose restrictive covenants that adversely impact our business. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we are unable to expand our operations or otherwise capitalize on our business opportunities due to such restrictions, our business, financial condition and results of operations could be materially adversely affected.

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 are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting 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, and may remain an "emerging growth company" for up to five years following the completion of our initial public offering, however, 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.

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors. In addition, under regulations recently adopted by the SEC, smaller reporting companies with less than $100 million in revenues are also exempt from obtaining an auditor attestation report on internal control over financial reporting.

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.

We must comply with laws, regulations and standards applicable to public companies, including evaluating our internal controls under Section 404 of the Sarbanes-Oxley Act of 2002, which requires significant cost and management attention, and any failure to comply with or adverse results from our compliance with such laws, regulations and standards could impact investor confidence and materially harm our business.

As a public company in the United States, and increasingly after we are no longer an "emerging growth company" or if we cease to be a "smaller reporting company," we are subject to laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and regulations implemented by the SEC and Nasdaq, that are subject to varying interpretations and may evolve over time as new guidance is provided by regulatory and governing bodies. We have invested and intend to continue to invest resources to comply with such laws, regulations and standards, which may divert 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" or if we cease to be a "smaller reporting company" that

has less than $100 million in annual revenues, we will be required 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 SEC is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We have developed internal control procedures designed to comply with the requirements of Section 404, but our controls may not be adequate because of changes in conditions or the degree of compliance with our policies or procedures may deteriorate, or 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. 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. Furthermore, remediation of any identified material weaknesses, such as a requirement to issue a financial statement restatement, may cause delays in our filing of quarterly or annual financial results, which could limit our ability to raise capital, and may create a significant strain on our internal resources, increase our costs, cause management distraction and significantly affect our stock price in an adverse manner.

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.

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.

Previously, we reported a claim filed in the Superior Court of the State of Delaware regarding a former consultant of the Company who was compensated in cash and stock options for his services, demanding damages of up to approximately $3.6 million plus punitive damages in connection with a delay in such consultant's ability and timing to exercise options and sell shares of our common stock related to past consulting services. As previously disclosed, we strongly deny any wrongdoing alleged in the threatened litigation and firmly believe the allegations in the complaint are entirely without merit and intend to defend against them vigorously. On October 15, 2019, the court granted our motion to dismiss and concluded the plaintiff failed to sufficiently assert claims. On November 6, 2019, the plaintiff filed a notice of appeal to the Delaware Supreme Court. Briefing on the plaintiff's appeal was completed on February 21, 2020. No decision has been rendered yet by the Delaware Supreme Court. We are unable to estimate the amount of a potential loss or range of potential loss, if any.

Other than as described above, we are not currently a party to any legal or governmental regulatory proceedings, nor is our management aware of any pending or threatened legal or government regulatory proceedings proposed to be initiated against us that would have a material adverse effect on our business, financial condition or operating results.

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 Monster Merger, further described in "Note 1—Summary of Significant Accounting Policies" to the accompanying financial statements included in this Annual Report on Form 10-K. In connection with the Monster 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."

Subject to and upon completion of the RDD Merger, we plan to change our name to 9 Meters Biopharma, Inc. and the trading symbol for the common stock will change to "NMTR."

Holders

As of March 17, 2020, there were approximately 255 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 for the development and growth of our business. The declaration of any future cash dividend, if any, would be at the discretion of the Board and would depend upon our earnings, if any, our capital requirements and financial position, general economic conditions and other factors that the Board consider to be relevant.

Recent Sales of Unregistered Securities

On December 19, 2019, we and each of the purchasers of the April Warrants and Placement Agent Warrants entered into separate exchange agreements pursuant to which we agreed to issue to the purchasers an aggregate of 5,441,023 shares of our common stock at a ratio of 1.2 exchange shares for each purchaser warrant in exchange for the cancellation and termination of all of the 4,534,186 outstanding purchaser warrants (the "Exchange"). The Exchange will be made in reliance upon the exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended.

Item 6. Selected Financial Data.

Not applicable.

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

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 of Monster and Private Innovate, or the Monster Merger, on January 29, 2018, and, where applicable, the business of Private Innovate prior to the Monster Merger. All references to "Monster" refer to Monster Digital, Inc. prior to the closing of the Monster Merger.

The following analysis reflects the historical financial results of Private Innovate prior to the Monster Merger and that of Innovate following the Monster Merger and does not include the historical financial results of Monster. All share and per share disclosures have been retroactively adjusted to reflect the exchange of shares in the Monster Merger.

The following discussion of our financial condition and results of operations should be read in conjunction with our audited financial statements and the related notes thereto included elsewhere in this Annual Report on Form 10-K. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. 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 the "Risk Factors" in Part I, Item 1A of this report.

Company Overview

Innovate

We are a clinical-stage biopharmaceutical company developing novel medicines for autoimmune and inflammatory diseases with unmet medical needs, including drug candidates for celiac disease, ulcerative colitis (UC), nonalcoholic steatohepatitis (NASH), alcoholic steatohepatitis (ASH) and Crohn's disease. In 2019, we started the Phase 3 clinical trial for our lead drug candidate, larazotide acetate or larazotide (INN-202), for the treatment of celiac disease. Larazotide has the potential to be the first-to-market therapeutic for celiac disease, an unmet medical need affecting an estimated 1% of the U.S. population or more than 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. In celiac disease, larazotide is the only drug which has successfully met its primary endpoint with statistical significance in a Phase 2b efficacy trial, which was comprised of 342 patients. We completed the End of Phase 2 meeting with the FDA for the treatment of celiac disease with larazotide and received

Fast Track designation. Larazotide has been shown to be safe and effective after being tested in several clinical trials involving nearly 600 patients, most recently in the Phase 2b trial for celiac disease. We have approximately 100 active clinical trial sites with three treatment groups, 0.25 mg of larazotide, 0.5 mg of larazotide and a placebo arm. Site activation and patient enrollment have been impacted by the announcement of the RDD Merger and the winter holiday season. We continue to monitor the evolving situation with COVID-19, which is likely to directly or indirectly impact the pace of enrollment over the next several months. We currently anticipate a top-line readout from the trial in 2021.

INN-108 is a novel oral small molecule therapeutic for UC, which affects approximately 1.4 million individuals in the U.S. alone. With the combination of an immunomodulator, INN-108 could lead to a more efficacious drug than the current 5-ASA/mesalamine formations being used to treat UC. A Phase 1 trial was successfully completed in the U.S. with 24 subjects. We may prepare for a phase 2 trial in UC, subject to receipt of additional financing.

Intestinal permeability is compromised in numerous diseases where a disruption of the epithelial barrier that separates the lumen from the host's immune system may contribute to uncontrolled inflammation. Larazotide is a gut-restricted peptide which has been shown to re-normalize intestinal permeability in various inflammatory and metabolic preclinical models. During 2019, we initiated a research collaboration with Institut Gustave Roussy's Laurence Zitovogel, MD, Ph.D., Department of Immuno-oncology. Through this collaboration, we seek to understand how the therapeutic effect of immune checkpoint inhibitors, such as antibodies to CTLA-4 and PD-1, are modulated by blocking translocation of certain metabolites and bacterial antigens and toxins from interacting with the host immune system in pre-clinical oncology models. Building on previous research that showed a type of permeability known as "leaky gut" that may cause microbial translocation of toxic products into circulation of the bloodstream, we are expanding our work in liver disease. Initial *in vitro* data suggests the potential use of larazotide in alcoholic liver diseases. We entered into a research collaboration with Massachusetts General Hospital to explore larazotide in animal models for the treatment of ASH.

Monster Merger

On January 29, 2018, Monster and Private Innovate completed a reverse recapitalization in accordance with the terms of the Monster Merger Agreement. In connection with the transaction, Private Innovate changed its name to IB Pharmaceuticals Inc. Pursuant to the Monster Merger Agreement, Monster Merger Sub merged with and into IB Pharmaceuticals with IB Pharmaceuticals surviving as the wholly owned subsidiary of Monster. Immediately following the Monster Merger, Monster changed its name to Innovate Biopharmaceuticals, Inc. On March 29, 2018, IB Pharmaceuticals was merged into Innovate and ceased to exist.

The Monster Merger is further described in "Note 1—Summary of Significant Accounting Policies" and "Note 3—Monster Merger and Financing" to the accompanying financial statements included in this Annual Report on Form 10-K.

Agreement and Plan of Merger and Reorganization with RDD Pharma, Ltd.

On October 6, 2019, we entered into the RDD Merger Agreement, pursuant to which we agreed to acquire all of the outstanding capital stock of privately-held RDD, an Israel corporation, in exchange for a combination of common and preferred shares to be issued by us. The RDD Merger will include a concurrent capital raise led by OrbiMed Advisors LLC, with a minimum funding requirement of $10 million. We are targeting completion of the RDD Merger and RDD Merger Financing near the end of the first quarter of 2020. Upon closing of the RDD Merger, on an as-converted, fully diluted basis, our current stockholders will own approximately 62% of the combined company's capital stock and the current RDD stockholders will own approximately 38% of the combined company's capital stock. The final ownership percentages are subject to dilution based on the final amount of capital invested in the RDD Merger Financing, which will dilute both the current Innovate stockholders and current RDD stockholders on a pro rata basis. We intend to use the proceeds from the RDD Merger Financing to advance our Phase 3 clinical trial for the treatment of celiac disease as well as for progression of RDD's current pipeline. Subject to and concurrently with the closing of the RDD Merger, the Board will appoint John Temperato, the Chief Executive Officer of RDD, as Chief Executive Officer of the combined company, 9 Meters Biopharma, Inc.

Financial Overview

Since our inception, we have focused our efforts and resources on identifying and developing our research and development programs. We have not had any products approved for commercial sale and have incurred operating losses in each year since inception. Substantially all of our operating losses resulted from expenses incurred in connection with our research and

development programs and from general and administrative costs associated with our operations. As of December 31, 2019, we had an accumulated deficit of $70.6 million. We incurred net losses of $27.0 million and $24.2 million for the years ended December 31, 2019 and 2018, respectively. We expect to continue to incur significant expenses and increase our operating losses for the foreseeable future, which may fluctuate significantly between periods. We anticipate that our expenses will increase substantially as and to the extent we:

- continue research and development, including preclinical and clinical development of our existing and future product candidates, including INN-202;
- complete integration of operations and personnel associated with the proposed RDD Merger;
- potentially seek regulatory approval for our product candidates;
- commercialize any product candidates for which we obtain regulatory approval;
- maintain and protect our intellectual property rights;
- add operational, financial and management information systems and personnel; and
- continue to incur additional legal, accounting, regulatory, tax-related and other expenses required to operate as a public company.

As such, we will need substantial additional funding to support our operating activities. Adequate funding may not be available to us on acceptable terms, or at all. We currently anticipate that we will seek to fund our operations through equity or debt financings, strategic alliances or licensing arrangements, or other sources of financing. Our failure to obtain sufficient funds on acceptable terms could have a material adverse effect on our business, results of operations and financial condition.

Other Recent Developments

In June 2019, we expanded our senior management team by appointing Edward J. Sitar as our Chief Financial Officer. Mr. Sitar has extensive experience in finance and the life sciences industry. Mr. Sitar is responsible for developing and implementing our financial strategy and growth plans.

In February 2019, we strengthened our clinical development team by appointing Patrick Griffin, M.D., F.A.C.P. as our Chief Medical Officer. Dr. Griffin has several decades of clinical development experience in gastroenterology, autoimmune and metabolic diseases and has overseen multiple phase 3 clinical trials.

Warrant Exchange

Pursuant to a purchase agreement dated April 29, 2019, we issued warrants to purchase up to 4,318,272 shares of our common stock, or the April Warrants, and granted the placement agent warrants to purchase up to 215,914 shares of common stock, or the Placement Agent Warrants. On December 19, 2019, we entered into separate exchange agreements with each of the purchasers of the April Warrants and the Placement Agent Warrants, or the Exchange Agreements. Pursuant to the Exchange Agreements, we agreed to issue to the purchasers an aggregate of 5,441,023 shares of our common stock, or the Exchange Shares, at a ratio of 1.2 Exchange Shares for each purchaser warrant in exchange for the cancellation and termination of all of the outstanding April Warrants and Placement Agent Warrants.

Warrant Extension and Offer to Amend and Exercise

Effective February 6, 2020, we entered into amendments with the holders of our outstanding short-term warrants originally issued March 18, 2019, or the Short-Term Warrants, to extend the exercise period of each Short-Term Warrant by six months. The Short-Term Warrants, as amended, are exercisable for up to an aggregate of 4,181,068 shares of our common stock, par value $0.0001 per share, until September 18, 2020. Except as specifically amended, the terms and conditions of each Short-Term Warrant remained in full force and effect and were not affected by this amendment. See “Note 1—Summary of Significant Accounting Policies” to the accompanying financial statements included in this Annual Report on Form 10-K for additional terms of the Short-Term Warrants.

On February 12, 2020, we offered to amend outstanding warrants to purchase an aggregate of 12,346,631 shares of common stock, or the Original Warrants, held by holders of certain outstanding warrants, or the Offer to Amend and Exercise. The Original Warrants of eligible holders who elect to participate in the Offer to Amend and Exercise will be amended to (i) shorten the

exercise period so that they expire concurrently with the closing of the RDD Merger and (ii) significantly reduce the exercise price per share. The amended warrants are required to be exercised for cash, and any cashless exercise provisions in the Original Warrants have been omitted.

Amendment to the 2012 Omnibus Incentive Plan

On December 4, 2018, our stockholders approved an amendment to the 2012 Omnibus Incentive Plan, or the Omnibus Plan, to provide for an additional 3,000,000 shares of common stock to be issued pursuant to the plan and an evergreen provision to automatically increase the number of shares issuable pursuant to the plan on an annual basis for the period commencing January 1, 2019 and ending on January 1, 2022. The plan will automatically terminate on April 30, 2022. Pursuant to the evergreen provision, on January 1, 2020 and 2019, the number of shares of common stock available under the Omnibus Plan automatically increased by 1,973,883 and 1,304,441 shares, respectively.

Research and Development Updates

During 2019, we dosed the first patient in our Phase 3 clinical trials for INN-202 in adult patients with celiac disease. We have approximately 100 active clinical trial sites, and we are targeting approximately 600 subjects in the first Phase 3 clinical trial with three treatment groups, 0.25 mg of larazotide tid, 0.5 mg of larazotide tid and a placebo arm. We currently anticipate a top-line readout from the trial in 2021.

Recent research and development milestones include:

- continued research collaboration with Institut Gustave Roussy to study regulation of intestinal permeability and the gut microbiota using larazotide in immuno-oncology checkpoint inhibitor failure preclinical models;
- continued research collaboration with Dr. Anthony Blikslager of North Carolina State University to explore life-cycle extension of our lead molecule larazotide acetate;
- initiated research collaboration with Dr. Younggeon Jin of University of Maryland, College Park, to understand tight junction biology; and
- continued research collaboration with Dr. James Nataro of the University of Virginia, Charlottesville to study larazotide’s effect on Environmental Enteric Dysfunction.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2018

The following table sets forth the key components of our results of operations for the years ended December 31, 2019 and 2018:

	Year Ended December 31,			
	2019	**2018**	**$ Change**	**% Change**
Operating expenses:				
Research and development	$ 13,715,968	$ 7,559,077	$ 6,156,891	81 %
General and administrative	10,566,813	10,664,991	(98,178)	(1)%
Warrant inducement expense	1,265,780	—	1,265,780	100 %
Total operating expenses	25,548,561	18,224,068	7,324,493	40 %
Loss from operations	(25,548,561)	(18,224,068)	(7,324,493)	(40)%
Total other expense, net	(1,500,247)	(5,938,211)	4,437,964	75 %
Net loss	$ (27,048,808)	$ (24,162,279)	$ (2,886,529)	(12)%

Research and Development Expense

Research and development expense for the year ended December 31, 2019 increased approximately $6.2 million, or 81%, as compared to the year ended December 31, 2018. The increase was driven primarily by an increase of approximately $7.6 million associated with progress in our Phase 3 clinical trial for INN-202. In addition, research and development license fees increased by approximately $0.3 million due to a milestone payment associated with dosing the first patient in our Phase 3 clinical trial. These increases were offset by decreases in (i) compensation costs and personnel benefits of $0.2 million primarily due to a decrease in severance expense associated with a former research and development executive and (ii) non-cash share-based compensation of approximately $1.5 million primarily due to a decrease in options granted and vested and a decrease in the fair value of options granted as a result of the decline in our stock price.

General and Administrative Expense

General and administrative expense for the year ended December 31, 2019 decreased approximately $0.1 million, or 1%, as compared to the year ended December 31, 2018. The decrease was primarily due to a decrease of approximately $1.4 million in accounting and legal fees associated with the Monster Merger. This decrease was offset by increases of (i) $0.6 million in non-cash share-based compensation expense primarily due to option modifications that extended the exercise periods of certain outstanding options; (ii) $0.4 million associated with operating as a public company, including directors' and officers' liability insurance premiums, investor relations costs and regulatory fees and services associated with maintaining compliance with Nasdaq exchange listing and SEC regulations; (iii) $0.2 million associated with compensation costs and personnel benefits for our general and administrative personnel; and (iv) $0.1 million in market research, business development, patent protection of our intellectual property and other general corporate costs. The increase in compensation costs and personnel benefits is primarily due to hiring a chief financial officer during the year ended December 31, 2019.

Warrant Inducement Expense

During the year ended December 31, 2019, we recognized warrant inducement expense of approximately $1.3 million. There was no warrant inducement expense during the year ended December 31, 2018. The warrant inducement expense represents the accounting fair value of consideration issued to induce conversion of the April Warrants and Placement Agent Warrants exchanged for 1.2 shares of our common stock per warrant, further described in "Note 1—Summary of Significant Accounting Policies" to the accompanying financial statements included in this Annual Report on Form 10-K.

Other Income (Expense), Net

Other expense, net, for the year ended December 31, 2019, decreased by approximately $4.4 million, or 75%, as compared to the year ended December 31, 2018. The decrease was primarily due to (i) a non-cash charge of $3.1 million for the beneficial conversion feature that was triggered when our convertible debt and accrued interest converted to our common stock at a 25% discount on January 29, 2018 but did not recur in 2019; (ii) non-cash interest expense of approximately $1.5 million for the amortization of debt discount; and (iii) $1.2 million associated with the change in fair value of the derivative liability. These decreases were offset by $1.0 million for the loss on extinguishment of debt in March 2019, $0.1 million associated with the change in fair value of warrant liabilities, and $0.3 million associated with the option agreement further described in "Note 6—Debt" to the accompanying financial statements included in this Annual Report on Form 10-K.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2019, we had cash and cash equivalents of approximately $4.6 million, compared to approximately $5.7 million as of December 31, 2018. The decrease in cash was primarily due to expenditures for business operations, research and development and clinical trial costs, offset by the net proceeds from the March 2019 Offering and April 2019 Offering, each as described below, in addition to the issuance of convertible debt, further described below.

We expect to incur substantial expenditures in the foreseeable future for the continued development and clinical trials of our product candidates. We will continue to require additional financing to develop our product candidates and fund operations for the foreseeable future. We plan to seek funds through debt or equity financings, strategic alliances and licensing arrangements, and other collaborations or sources of financing, including the RDD Merger Financing.

We expect to complete the RDD Merger and concurrent RDD Merger Financing near the end of the first quarter of 2020. However, the COVID-19 pandemic may affect access to capital and could impact the timing of the Company's proposed merger with RDD. The RDD Merger Financing contains a minimum funding requirement of $10 million. We plan to use the funds from the RDD Merger Financing to progress the Phase 3 clinical trial in celiac disease as well as for progression of RDD's current pipeline, including the SBS product candidate, NB-002 upon successful completion of the Naia Acquisition.

There can be no assurance that we will be able to complete the RDD Merger and RDD Merger Financing or raise the additional capital needed to continue our pipeline of research and development programs on terms acceptable to us, on a timely basis or at all. If we are unable to raise additional funds when needed, our ability to develop our product candidates will be impaired. We may also be required to delay, reduce, or terminate some or all of our development programs and clinical trials.

March 2019 Offering

On March 17, 2019, we entered into a purchase agreement with SDS Capital Partners II, LLC and certain other accredited investors, or the Purchase Agreement, pursuant to which we sold, on March 18, 2019, 4,181,068 shares of our common stock and issued Short-Term Warrants to purchase up to 4,181,068 shares of our common stock and long-term warrants to purchase up to 2,508,634 shares of common stock, or the March Long-Term Warrants. Pursuant to the Purchase Agreement, we issued shares of common stock and warrants at a purchase price per share of $2.33 for aggregate gross proceeds of approximately $9.7 million. For additional terms of the agreement, see "Note 1—Summary of Significant Accounting Policies" in the accompanying financial statements to this Annual Report on Form 10-K. Warrant holders who elect to participate in the Offer to Amend and Exercise, further described in "Recent Developments—Warrant Extension and Offer to Amend and Exercise," will have a significantly reduced exercise price per share.

Additional Issuance of Warrants

On April 25, 2019, we entered into an amendment to the Purchase Agreement with certain of the purchasers thereto, or the Amendment. The Amendment (i) deleted Section 4.12 of the Purchase Agreement, which generally prohibited us from issuing, entering into agreements to issue, announcing proposed issuances, selling or granting certain securities between the date of the Purchase Agreement and the date that was 45 days following the closing date thereunder and (ii) gave each purchaser the right to purchase, for $0.125 per underlying share, an additional warrant to purchase shares of our common stock having an exercise price per share of $2.13 and otherwise having the terms of the March Long-Term Warrants, collectively the New Warrants, pursuant to a securities purchase agreement to be entered into among the Company and each purchaser that desired to purchase

the New Warrants. On May 17, 2019, we and each purchaser entered into such securities purchase agreement, or the New Agreement, pursuant to which we issued New Warrants exercisable for an aggregate of 3,897,010 shares of our common stock.

The New Warrants are exercisable for five years beginning on the six-month anniversary of the date of issuance until the five-year anniversary of the date of issuance. The New Warrants have an initial exercise price of $2.13 per share, subject to certain adjustments. Warrant holders who elect to participate in the Offer to Amend and Exercise further described above in "Recent Developments—Warrant Extension and Offer to Amend and Exercise," will have a significantly reduced exercise price per share.

April 2019 Offering

On April 29, 2019, we entered into a purchase agreement pursuant to which we sold, on May 1, 2019, 4,318,272 shares of our common stock at a purchase price of $2.025 per share for aggregate gross proceeds of approximately $7.9 million, after deducting commissions and estimated offering costs, or the April Purchase Agreement. Pursuant to the April Purchase Agreement, we issued the April Warrants to purchase up to 4,318,272 shares of common stock at an initial exercise price of $2.13 per share. Additionally, we granted the Placement Agent Warrants to purchase up to 215,914 shares of common stock. The Placement Agent Warrants had substantially the same terms as the April Warrants, except that the Placement Agent Warrants had an exercise price of $2.53 per share and a term of 5 years from the effective date of the offering. For additional terms of the agreement, see "Note 1—Summary of Significant Accounting Policies" in the accompanying financial statements to this Annual Report on Form 10-K. Pursuant to the Exchange Agreements further described above in "Recent Developments—Warrant Exchange," we issued to the purchasers of the April Warrants and Placement Agent Warrants an aggregate of 5,441,023 shares of our common stock, or the Exchange Shares, at a ratio of 1.2 Exchange Shares for each purchaser warrant in exchange for the cancellation and termination of all of the outstanding April Warrants and Placement Agent Warrants. No proceeds were received in exchange for the April Warrants and Placement Agent Warrants.

Senior Convertible Note and Exchange Agreement

On January 29, 2018, we entered into a note purchase agreement and senior note payable, or the Note, with a lender. The principal amount of the Note was $4.8 million. The Note was issued at a discount of $1.8 million and net of financing costs, for total proceeds of $3.0 million. Interest on the Note accrued from January 29, 2018, at a rate of 12.5% per annum and quarterly payments of interest only were due beginning on March 30, 2018 and compounded quarterly. On October 4, 2018, we entered into an Amendment and Exchange Agreement, with the noteholder exchanging the Note for a new note, or the Senior Convertible Note. The principal amount of the Senior Convertible Note was $5.2 million and bore interest at a rate of 8% per annum, payable quarterly in cash, with a scheduled maturity date of October 4, 2020. The interest rate would automatically increase if there was an event of default to 18% per annum during the default period.

The Senior Convertible Note was convertible into shares of our common stock at certain conversion prices depending on certain factors, which include the volume weighted average price, or VWAP, of our common stock for a period of time prior to conversion. In addition, the Senior Convertible Note was redeemable by the noteholder or by us under certain qualifying conditions. In January 2019, the noteholder issued a redemption notice and we repaid the noteholder approximately $1.1 million of principal and accrued interest. During January 2019, we entered into an option to purchase Senior Convertible Note, or Option Agreement, with the noteholder. The Option Agreement provided us with the ability to repay the Senior Convertible Note prior to March 31, 2019, which we exercised in March 2019. We paid the noteholder approximately $0.3 million in consideration for the noteholder entering into the Option Agreement, which was recorded as interest expense in our accompanying statements of operations and comprehensive loss. On March 11, 2019, we exercised our repurchase rights from the Option Agreement and paid the noteholder of the Senior Convertible Note approximately $5.3 million, which was the full purchase amount, including interest, of the Senior Convertible Note pursuant to the terms of the Option Agreement. There are no further amounts outstanding under the Senior Convertible Note and the Senior Convertible Note has been canceled.

Amortization of the debt discount for the Note and Senior Convertible Note totaled approximately $2.5 million for the year ended December 31, 2018 and is recorded as interest expense in the accompanying statements of operations and comprehensive loss. There was no such expense related to the Note and Senior Convertible Note during the year ended December 31, 2019.

Unsecured Convertible Promissory Note

On March 8, 2019, we entered into a securities purchase agreement pursuant to which we issued an unsecured convertible promissory note, or the Unsecured Convertible Note, in the principal amount of $5.5 million. The holder of the Unsecured

Convertible Note, or the Convertible Noteholder, may elect to convert all or a portion of the Unsecured Convertible Note at any time and from time to time into our common stock at a conversion price of $3.25 per share, subject to adjustment for stock splits, dividends, combinations and similar events. We may prepay all or a portion of the Unsecured Convertible Note at any time for an amount equal to 115% of then outstanding obligations or the portion of the obligations we are prepaying. The purchase price of the Unsecured Convertible Note was $5.0 million and the Unsecured Convertible Note carries an original issuance discount of $0.5 million, which is included in the principal amount of the Unsecured Convertible Note. In addition, we agreed to pay $20,000 of transaction expenses, which were netted out of the purchase price of the Unsecured Convertible Note. We also incurred additional transaction costs of approximately $37,000, which were recorded as debt issuance costs. As a result of the redemption features of the Unsecured Convertible Note, further described in "Note 6—Debt," we are amortizing the debt issuance costs and accreting the OID to interest expense over the estimated redemption period of 15 months, using the effective interest method.

The various conversion and redemption features contained in the Unsecured Convertible Note are embedded derivative instruments, which were recorded as a debt discount and derivative liability at the issuance date at their estimated fair value of $1.3 million. Amortization of debt discount and accretion of the OID for the Unsecured Convertible Note recorded as interest expense was approximately $1.1 million for the year ended December 31, 2019.

The Unsecured Convertible Note bears interest at the rate of 10% (which will increase to 18% upon and during the continuance of an event of default) per annum, compounding on a daily basis. All principal and accrued interest on the Unsecured Convertible Note is due on the second-year anniversary of the Unsecured Convertible Note's issuance. During the year ended December 31, 2019, we made principal payments of $1.5 million under the Unsecured Convertible Note.

At any time after the six-month anniversary of the issuance of the Unsecured Convertible Note, (i) if the average volume weighted average price over 20 trading dates exceeds $10.00 per share, we may generally require that the Unsecured Convertible Note convert into shares of our common stock at the $3.25 (as adjusted) conversion price, and (ii) the Convertible Noteholder may elect to require all or a portion of the Unsecured Convertible Note be redeemed by us. If the Convertible Noteholder requires a redemption, we, at our discretion, may pay the redeemed portion of the Unsecured Convertible Note in cash or in our common stock at a conversion rate equal to the lesser of (i) the $3.25 (as adjusted) conversion rate or (ii) 80% of the average of the five lowest volume weighted-average prices of our Common Stock over the preceding 20 trading days. The Convertible Noteholder may not redeem more than $500,000 per calendar month during the period between the six-month anniversary of the date of issuance until the first-year anniversary of the date of issuance and $750,000 per calendar month thereafter. Our obligation or right to deliver our shares upon the conversion or redemption of the Unsecured Convertible Note is subject to a 19.99% cap and subject to a floor price trading price of $3.25 (unless waived by us). Any amounts elected to be redeemed once the cap is reached or if the market price is less than the $3.25 floor price must be paid in cash. In addition, we will be required to pay in cash any amounts elected to be redeemed by the noteholder if any of the following conditions are not satisfied as of the date the noteholder delivers a notice of redemption: (i) all conversion shares are freely tradable under Rule 144 of the Securities Act without the need for registration under applicable federal and state securities laws (without regard to any limitation on conversion of the notes), (ii) no Event of Default (as defined in the applicable note) has occurred and is continuing, (iii) the average and median daily dollar volume of our common stock for the prior 20 and 200 trading days is greater than $250,000, (iv) the five-day volume weighted-average price of our common stock is at least $1.00 per share and (v) our market capitalization is at least $15 million.

If there is an Event of Default under the Unsecured Convertible Note, the Convertible Noteholder may accelerate our obligations or elect to increase the outstanding obligations under the Unsecured Convertible Note. The amount of the increase ranges from 5% to 15% depending on the type of default (as defined in the Unsecured Convertible Note). In addition, the Unsecured Convertible Note obligations will be increased if there are delays in our delivery requirements for the shares or cash issuable upon the conversion or redemption of the Unsecured Convertible Note in certain circumstances.

If we issue convertible debt in the future with any terms, including conversion terms, that are more favorable to the terms of the Unsecured Convertible Note, the Convertible Noteholder may elect to incorporate the more favorable terms into the Unsecured Convertible Note. For further details describing our debt obligations, see "Note 6—Debt" to the accompanying financial statements included in this Annual Report on Form 10-K.

Additional Convertible Note

On January 10, 2020, we entered into an additional securities purchase agreement pursuant to which we issued an unsecured convertible promissory note to the Convertible Noteholder in the principal amount of approximately $2.8 million, or the Additional Note. The Convertible Noteholder, may elect to convert all or a portion of the Additional Note at any time and from

time to time into our common stock at a conversion price of $3.25 per share, subject to adjustment for stock splits, dividends, combinations and similar events. We may prepay all or a portion of the Additional Note at any time for an amount equal to 115% of then outstanding obligations or the portion of the obligations we are prepaying. The purchase price of the Additional Note was $2.5 million and carries an original issuance discount of $0.3 million, which is included in the principal amount of the Additional Note. In addition, we agreed to pay $20,000 of transaction expenses, which were netted out of the purchase price of the Additional Note.

The Additional Note has almost entirely the same terms as the Unsecured Convertible Note. See “Note 12—Subsequent Events” to the accompanying financial statements included in this Annual Report on Form 10-K for further details regarding the terms of the Additional Note.

At-the-market Offering

On October 26, 2018, we entered into a common stock sales agreement with H.C. Wainwright & Co., LLC and Ladenburg Thalmann & Co. Inc. and filed a prospectus with the SEC related to such offering. We previously filed a Form S-3 that became effective on July 13, 2018 that included the registration of $40 million of our shares of common stock in connection with a potential “at-the-market” offering. Pursuant to the sales agreement, we may issue and sell shares having an aggregate gross sales price of up to $40 million. During the years ended December 31, 2019 and 2018, we sold 705,714 and 17,576 shares under the “at the market” offering, respectively, for net proceeds of approximately $1.7 million. Effective March 19, 2020, we terminated the ATM facility.

Cash Flows

The following table sets forth the primary sources and uses of cash for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	**2018**
Net cash (used in) provided by:		
Operating activities	$ (17,967,992)	$ (15,169,330)
Investing activities	(11,934)	(13,943)
Financing activities	16,843,958	20,556,610
Net increase (decrease) in cash and cash equivalents	$ (1,135,968)	$ 5,373,337

Operating Activities

For the year ended December 31, 2019, net cash used in operating activities of approximately $18.0 million primarily consisted of a net loss of $27.0 million and a non-cash gain of $1.2 million for the extinguishment of the Senior Convertible Note derivative liability and changes in the fair value of the warrant liabilities and the Unsecured Convertible Note derivative liability. These decreases were offset by adjustments for non-cash share-based compensation of approximately $2.9 million, non-cash warrant inducement expense of $1.3 million, non-cash loss of $1.0 million on the extinguishment of debt, non-cash interest expense of approximately $1.1 million, write-off of deferred offering costs associated with the ATM facility of $0.1 million and a net change of approximately $3.9 million due to changes in operating assets and liabilities.

For the year ended December 31, 2018, net cash used in operating activities of approximately $15.2 million primarily consisted of a net loss of $24.2 million, offset by adjustments for non-cash share-based compensation of approximately $3.8 million, beneficial conversion feature of $3.1 million, non-cash interest expense of approximately $2.8 million offset by the change in fair value of derivative liability of $0.1 million and a net change totaling approximately $0.7 million due to increases in prepaid expense, accounts payable and other current assets and accounts payable and decreases in accrued expenses.

Investing Activities

For the year ended December 31, 2019, net cash used in investing activities of approximately $12,000 represented the purchase of computer equipment. Net cash used in investing activities for the year ended December 31, 2018, represented the purchase of office furniture and computer equipment of approximately $14,000. In addition, we received loan payments from a related party of $75,000 which was offset by an investment in a certificate of deposit of $75,000.

Financing Activities

For the year ended December 31, 2019, net cash provided by financing activities of approximately $16.8 million primarily consisted of (i) $20.7 million received from the sale of our common stock and warrants and (ii) $5.0 million received from the issuance of the Unsecured Convertible Note. These increases were offset by approximately $7.8 million in debt repayments, approximately $1.0 million in stock issuance costs and approximately $0.1 million in debt issuance costs.

For the year ended December 31, 2018, net cash provided by financing activities of approximately $20.6 million primarily consisted of (i) $18.1 million received from the sale of our common stock and warrants in the Equity Issuance; (ii) $3.0 million from the issuance of a note payable; (iii) $0.9 million from the exercise of warrants and (iv) $0.2 million in proceeds from the exercise of stock options. These increases were offset by approximately $1.5 million in stock issuance costs and $0.2 million in payment of deferred offering costs.

Capital Requirements

We have not generated any revenue from product sales or any other activities. We do not expect to generate significant revenue unless and until we obtain regulatory approval of and commercialize, or out-license, one or more of our product candidates and do not know when, or if, these will occur. In addition, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. In addition, subject to obtaining regulatory approval of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations, including increased costs associated with being a public company and integrating the operations of RDD if the RDD Merger is successful.

The accompanying financial statements have been prepared on a basis which assumes that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Based on our limited operating history and recurring operating losses, there is substantial doubt that we will continue as a going concern for at least one year following the date of this Annual Report on Form 10-K, without additional financing. Management's plans with regard to these matters include entering into strategic partnerships or seeking additional debt or equity financing arrangements or a combination of these activities. 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. The accompanying financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

Contractual Obligations and Commitments

In October 2017, we entered into a three-year lease agreement for office space that expires on September 30, 2020 and includes a two-year renewal option. Base annual rent is $60,000. Monthly rent payments of $5,000 are due in advance of the first day of each month for the 24-month term. A security deposit of approximately $5,000 was paid in October 2017 and is included in other assets on the accompanying balance sheets included in the financial statements to this Annual Report on Form 10-K.

Effective January 1, 2019, we adopted ASC 842 using the modified retrospective approach. On the adoption date, we estimated the present value of the lease payments over the remaining term of the lease using a discount rate of 12%, which represented our estimated incremental borrowing rate. The two-year renewal option was excluded from the lease payments as we concluded the exercise of this option was not considered reasonably certain. See "Note 11—Commitments and Contingencies" to the accompanying financial statements included in this Annual Report on Form 10-K for further details regarding the impact of adopting ASC 842.

In November 2018 and February 2019, we entered into separation and general release agreements with two former executives that included separation benefits consistent with each former executive's employment agreement. We recognized severance expense totaling $0.3 million during the year ended December 31, 2019, that is being paid in equal installments over 12 months beginning February 2019. In addition, we recognized severance expense totaling $0.3 million during the year ended December 31, 2018, that is being paid in equal installments over 12 months beginning November 2018. The remaining accrued severance obligation in respect of the two former executives is $41,000 as of December 31, 2019, which is included in accrued expenses on the accompanying balance sheet.

We are obligated to make future payments to third parties under in-license agreements, including sublicense fees, royalties and payments that become due and payable on the achievement of certain development and commercialization milestones. As the amount and timing of sub-license fees and the achievement and timing of these milestones are not probable and estimable, such commitments have not been included on the accompanying balance sheets.

We also enter into agreements in the normal course of business with contract research organizations and other third parties with respect to services for clinical trials, clinical supply manufacturing and other operating purposes that are generally terminable by us with thirty to ninety days advance notice.

For further details, see "Note 11—Commitments and Contingencies" to the accompanying financial statements included in this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

As of December 31, 2019, we had no off-balance sheet arrangements as defined in Item 303(a)(4) of Regulation S-K as promulgated by the SEC.

Critical Accounting Policies and Use of Estimates

Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

Critical Accounting Policies

While our significant accounting policies are more fully described in the notes to our financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our financial statements and understanding and evaluating our reported financial results.

Areas of our financial statements where estimates may have the most significant effect include fair value measurements, accrued expenses, share-based compensation, income taxes and management's assessment of our ability to continue as a going concern. Changes in the facts or circumstances underlying these estimates could result in material changes and actual results could differ from these estimates.

Fair Value Measurements

We account for derivative instruments in accordance with Accounting Standards Codification ("ASC") 815, *Derivative and Hedging*, which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value. Our derivative financial instruments consist of embedded options in our convertible debt. The embedded derivatives include provisions that provide the noteholder with certain conversion and put rights at various conversion or redemption values as well as certain call options for us.

The fair value of the embedded derivatives issued in connection with the convertible debt financings was determined by using a Monte Carlo simulation technique ("MCS") to value the embedded derivative associated with each note. As part of the MCS valuation a discounted cash flow ("DCF") model is used to value the debt on a stand-alone basis and determine the discount rate to utilize in both the DCF and MCS models. The significant estimates used in the DCF model include the time to maturity of the convertible debt and calculated discount rate, which includes an estimate of our specific risk premium. The MCS methodology calculates the theoretical value of an option based on certain parameters, including (i) the threshold of exercising the option, (ii) the price of the underlying security, (iii) the time to expiration or expected term, (iv) the expected volatility of the underlying security, (v) the risk-free rate and (vi) the number of paths. We recognized a gain of approximately $0.9 million for the change in fair value of derivative liability during the year ended December 31, 2019 and a gain of approximately $0.4 million for the extinguishment of derivative liability.

The Short-Term Warrants, March Long-Term Warrants, New Warrants, April Warrants and Placement Agent Warrants that we issued during the year ended December 31, 2019 are freestanding financial instruments that contain net settlement options and may require us to settle these warrants in cash under certain circumstances. The March Long-Term Warrants and New Warrants are collectively referred to as the Long-Term Warrants. The April Warrants and Placement Agent Warrants are collectively referred to as the Exchange Warrants. We have classified these warrants as liabilities on the accompanying balance sheet. The warrant liabilities are initially recorded at fair value on the date of grant and will be subsequently re-measured to fair value at each balance sheet date until the warrant liabilities are settled. Changes in the fair value of the warrants are recognized as a non-cash component of other income and expense in the accompanying statements of operations and comprehensive loss.

Upon a fundamental transaction (as defined in the applicable warrant agreement), each holder of Short-Term Warrants, Long-Term Warrants and Exchange Warrants can elect to require us or a successor entity to purchase such holder's outstanding, unexercised warrants for a cash payment (or under certain circumstances other consideration) equal to the Black-Scholes value of the warrants on the date of consummation of the fundamental transaction, calculated in accordance with the terms and using the assumptions specified in the applicable warrant agreement. Due to the proposed RDD Merger, described further in "Note 1—Summary of Significant Accounting Policies," management has assumed that warrant holders would elect to receive cash payments under the applicable warrant agreements following the completion of the transaction. As such, the fair value of the warrants as of December 31, 2019, was determined, for financial reporting purposes, through the use of the Black-Scholes model, which resulted in a significant change in the fair value estimate compared to prior periods. The estimates underlying the assumptions used in both the MCS model and Black-Scholes model are subject to risks and uncertainties and may change over time, and the assumptions used in both the MCS model and the Black-Scholes model for financial reporting purposes generally differ from the assumptions that would be applied in determining a payout under the applicable warrant agreements. In addition, in accordance with the terms of the RDD Merger Agreement, we entered into Exchange Agreements and issued an aggregate of 5,441,023 shares of common stock at a ratio of 1.2 exchange shares in exchange for the cancellation and termination of the Exchange Warrants. The warrants exchanged prior to December 31, 2019, are not included in the valuation of warrant liabilities as of December 31, 2019.

The valuation technique utilized for our derivative liability and warrant liabilities involves management's estimates and judgment based on unobservable inputs and is classified in Level 3. Changes to estimates and assumptions used in estimating the fair value of an instrument may produce materially different values and could have a material impact to our reported net losses in future periods. See "Note 1—Summary of Significant Accounting Policies" and "Note 6—Debt" to the accompanying financial statements included in this Annual Report on Form 10-K for additional details regarding the accounting policy and fair value assumptions used in accounting for our fair value instruments.

Accrued Expenses

We incur periodic expenses such as cost associated with clinical trials and non-clinical activities, manufacturing of pharmaceutical active ingredients and drug products, regulatory fees and activities, fees paid to external service providers and consultants, salaries and related employee benefits and professional fees. We are required to estimate our accrued expenses, which involves reviewing quotations and contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice monthly in arrears for services performed or when contractual milestones are met. We estimate accrued expenses as of each balance sheet date based on facts and circumstances known at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

Costs incurred in research and development of products are charged to research and development expense as incurred. Costs for preclinical studies and clinical trial activities are recognized based on an evaluation of the vendors' progress towards completion of specific tasks, using data such as patient enrollment, clinical site activations or information provided by vendors regarding the actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which services are performed. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of clinical trials, or the services completed. Nonrefundable advance payments for goods or services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made. The estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. Although we do not expect our estimates to be materially different from those actually incurred, our estimates and assumptions

could differ significantly from actual costs, which could result in increases or decreases in research and development expenses in future periods when actual results are known.

Share-based Compensation

We account for share-based compensation using the fair value method of accounting which requires all such compensation to employees, including the grant of employee stock options, to be recognized in the statements of operations based on its fair value at the grant date. The expense associated with share-based compensation is recognized on a straight-line basis over the requisite service period of each award; however, the amount of compensation expense recognized at any date must be at least equal to the portion of the grant-date value of the award that is vested at that date.

We adopted ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Non-employee Share-Based Payment Accounting* effective January 1, 2019. ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. Beginning on the adoption date, we changed our expense recognition for share-based payments to non-employees to an amount determined at the grant or modification date instead of a variable amount to be re-measured each reporting period. We calculated the fair value of our non-employee grants as of the adoption date and determined that there was no impact to our accumulated deficit or other components of equity upon adoption of ASU 2018-07. The unamortized expense for non-employee grants will be recognized on a straight-line basis over the remaining contractual term of the respective non-employee option agreements.

We estimate the fair value of our stock-based awards to employees and non-employees using the Black-Scholes option pricing model, which requires the input of valuation assumptions, some of which are highly subjective. Key valuation assumptions include:

- *Expected dividend yield:* the expected dividend is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock.

- *Expected stock price volatility:* due to our limited historical trading data as a public company, the expected volatility is derived from the average historical volatilities of publicly traded companies within the same industry that we consider to be comparable to our business over a period approximating the expected term. In evaluating comparable companies, we consider factors such as industry, stage of life cycle, financial leverage, size and risk profile.

- *Risk-free interest rate:* the risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities approximately equal to the expected term.

- *Expected term:* the expected term represents the period that the stock-based awards are expected to be outstanding. Our historical stock option exercise data does not provide a reasonable basis upon which to estimate an expected term for employees due to a lack of sufficient data. Therefore, we estimate the expected term by using the simplified method provided by the SEC. The simplified method calculates the expected term as the average of the time-to-vesting and the contractual life of options. The expected term for non-employees is the contractual life of the option.

Income Taxes

No provision for federal and state income tax expense has been recorded for the years ended December 31, 2019 and 2018 due to the valuation allowance recorded against the net deferred tax asset and recurring losses. Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

As of December 31, 2019, we have net operating loss carryforwards for federal and state income tax purposes of approximately $42,944,800 and $42,349,200, respectively. Federal loss carryforwards of $3,551,900 begin to expire in 2034 and $39,392,900 of the federal losses carryforward indefinitely. The state loss carryforwards begin to expire in 2029. As of December 31, 2019, we have contribution carryforwards of approximately $10,300, which begin to expire in 2021. In addition, we have federal research and development credits of $723,800, which begin to expire in 2038.

The Internal Revenue Code of 1986, as amended, contains provisions which limit the ability to utilize the net operating loss and tax credit carryforwards in the case of certain events, including significant changes in ownership interests. If our net operating

loss and tax credit carryforwards are limited, and we have taxable income which exceeds the permissible yearly net operating loss and tax credit carryforwards, we would incur a federal income tax liability even though net operating loss and tax credit carryforwards would be available in future years.

Recent Accounting Pronouncements

For details of recent accounting pronouncements that we have adopted and our evaluation of their adoption on our financial statements, see "Note 1—Summary of Significant Accounting Policies—Recently Issued Accounting Standards" to the accompanying financial statements included 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.

None.

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, 2019. 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, 2019, 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 designed 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)*. Management identified a material weakness in internal control over financial reporting in connection with our audited financial statements for the year ended December 31, 2018, due to our inability to adequately segregate duties as a result of our limited number of accounting personnel. In an effort to remediate this material weakness during the year ended December 31, 2019, we added two full-time finance positions, a Chief Financial Officer who is serving as Principal Financial Officer and Principal Accounting Officer and a Controller. During the year ended December 31, 2019, we also enhanced our system of internal controls, including improving our segregation of duties. However, management determined that as of December 31, 2019, this material weakness still remains.

Although we are committed to continuing to improve our internal control processes and intend to implement a plan to remediate our material weakness after completion of the RDD Merger, 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 improper use of our assets. 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

During the fourth quarter of 2019, there were no material changes in our 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.

None

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Directors

The Board is divided into three classes for future elections. Each class consists, as nearly as possible, of one-third of the total number of directors, and except for a transition period, each class has a three-year term. For a transition period necessary

to fully implement the staggered three-year terms, the initial term for our Class II directors will expire at our annual meeting of stockholders in 2020 and the initial term for our Class III directors will expire at our annual meeting of stockholders in 2021. After such transition period, each class will be elected for a three-year term. The three-year term for our Class I directors will expire at our annual meeting of stockholders in 2022.

Certain information about our directors, including their ages as of March 17, 2020, and the expiration dates of their current terms of board service are provided in the table below. Additional biographical descriptions are set forth in the text below the tables and include the primary individual experience, qualifications, attributes and skills of each director that led to the conclusion that such director should serve as a member of the Board at this time.

Director	Age	Class	Current Term Expiration
Lorin K. Johnson, Ph.D.	67	Class I	2022 Annual Meeting of Stockholders
Roy Proujansky, M.D.	63	Class I	2022 Annual Meeting of Stockholders
Anthony E. Maida III, Ph.D., M.A., M.B.A.	68	Class II	2020 Annual Meeting of Stockholders
Saira Ramasastry, M.S., M. Phil.	44	Class II	2020 Annual Meeting of Stockholders
Jay Madan, M.S.	54	Class III	2021 Annual Meeting of Stockholders
Sandeep Laumas, M.D.	51	Class III	2021 Annual Meeting of Stockholders

Lorin K. Johnson, Ph.D. Dr. Johnson joined the 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., a Nasdaq-listed specialty pharmaceutical company, and held senior leadership positions there prior to its $15.8 billion acquisition by Valeant Pharmaceuticals International, Inc. 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 Glycyx MOR, LTD and Kinisi Therapeutics, Ltd., both GI specialty pharma companies based on the Isle of Man, Intact Inc., a GI specialty drug delivery company based in Belmont, CA and Tumour Trace Ltd, a cancer diagnostic company based in Nottingham, UK. 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 22 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 the Board.

Roy Proujansky, M.D. Dr. Proujansky joined the Board in January 2018. He is a pediatric gastroenterologist who 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 from July 2013 until his retirement in August 2019. Before serving in this role, 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 the Board.

Anthony E. Maida III, Ph.D., M.A., M.B.A. Dr. Maida joined the Board in January 2018 and serves as the chair of the audit committee and is a member of the compensation committee and the nominating and corporate governance committee. 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 Vitality Biopharma, Inc. (OTCQB: VBIO) and was formerly a member of the board of directors and audit chair of OncoSec Medical Inc. (OTCQB: ONCS) and Spectrum Pharmaceuticals, Inc. (Nasdaq GS: SPPI). 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 the Board.

Saira Ramasastry, M.S., M. Phil. Ms. Ramasastry has served as a member of the Board since June 2018 and serves as the chair of the compensation committee and is a member of the audit committee and the nominating and corporate governance committee. Since April 2009, she has served as Managing Partner of Life Sciences Advisory, LLC, a company that she founded to provide strategic advice, business development solutions and innovative financing strategies for the life science industry. From August 1999 to March 2009, Ms. Ramasastry was an investment banker with Merrill Lynch & Co., Inc. where she helped establish the biotechnology practice and was responsible for origination of mergers and acquisitions, strategic and capital markets transactions. Prior to joining Merrill Lynch she served as a financial analyst in the mergers and acquisitions group at Wasserstein Perella & Co., an investment banking firm, from July 1997 to September 1998. Ms. Ramasastry currently serves on the board of directors of Sangamo Therapeutics Inc. (Nasdaq: SGMO), Cassava Sciences, Inc. (Nasdaq: SAVA), and Glenmark Pharmaceuticals, Ltd., biotechnology companies, on the Industry Advisory Board of the Michael J. Fox Foundation for Parkinson's Research, and as business and sustainability lead for the European Prevention of Alzheimer's Dementia consortium. Ms. Ramasastry received her B.A. in economics with honors and distinction and an M.S. in management science and engineering from Stanford University, as well as an M. Phil. in management studies from the University of Cambridge where she is a guest lecturer for the Bioscience Enterprise Programme and serves on the Cambridge Judge Business School Advisory Council. Ms. Ramasastry is also a Health Innovator Fellow of the Aspen Institute and a member of the Aspen Global Leadership Network.

We believe that Ms. Ramasastry's experience in the life science industry as well as her experience on public company boards qualifies her to serve on the Board.

Sandeep Laumas, M.D. Dr. Laumas was appointed our Chief Executive Officer in February 2019 and has also served as our executive chairman since joining Private Innovate in 2014. 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. In August 2007, Dr. Laumas founded Bearing Circle Capital, an investment vehicle, and has served as its Managing Director since such time. 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 the Board.

Jay P. Madan, M.S. Mr. Madan founded Private Innovate in 2012 and began serving as its president and as a member of its board of directors at such time. Upon completion of the Merger, he became president and a member of the board of directors of Innovate Biopharmaceuticals, Inc. In March 2018, Mr. Madan was appointed as our chief business officer and serves as our Interim Principal Financial Officer and Interim Principal Accounting 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 the Board.

Executive Officers

For information regarding Dr. Laumas and Mr. Madan, please see above under "Directors."

Patrick Griffin, M.D., F.A.C.P. Dr. Griffin became our Chief Medical Officer in February 2019. Previously Dr. Griffin served as Executive Vice President and Chief Medical Officer of Synergy Pharmaceuticals from January 2015 through November 2018, and Senior Vice President and Chief Medical Officer from May 2013 through January 2015. From March 2012 to April 2013, Dr. Griffin served as Chief Medical Officer and Senior Vice President of Development at ImmusanT, Inc. From March 2009 until January 2012, Dr. Griffin served as Associate Vice President, Clinical Development and Head of External Innovation at Sanofi-Aventis (now Sanofi). He is a board-certified physician in both internal medicine and gastroenterology, and is a Fellow of the American College of Physicians. He received his medical degree from Columbia University, completing a residency in internal medicine at Presbyterian Hospital in New York, and a fellowship in gastroenterology at Brigham and Women's Hospital in Boston. Following his residency and fellowship, Dr. Griffin joined the medical faculty of Columbia College of Physicians and Surgeons, where he held a number of academic, clinical research, teaching and management positions, and maintained a private practice in New York.

Edward J. Sitar. Mr. Sitar became our Chief Financial Officer in July 2019. Most recently he served as the Chief Financial Officer of Ammon Analytical Laboratory, a company focused on specialty testing for the drug treatment community, from April 2017 to November 2018. Previously, he served as the Chief Financial Officer of Cancer Genetics, Inc. (CGIX), a company focused on precision medicine for oncology, from March 2014 until February 2017. Prior to his service at Cancer Genetics, he served from January 2013 to December 2013 as the Chief Financial Officer-New Business of Healthagen, an Aetna company offering health products and services, and served as Chief Financial Officer of ActiveHealth Management from August 2010 to December 2012. From April 2001 to May 2010, he served as Executive Vice President and Chief Financial Officer of Cadent Holdings, Inc., a privately-held company that provided three-dimensional digital scanning services for dentists and orthodontists. From August 1998 to April 2001, Mr. Sitar served as Chief Financial Officer and Treasurer of MIM Corporation, now BioScrip, Inc., a publicly traded specialty pharmaceutical and pharmacy benefit management service provider. From May 1996 to August 1998, Mr. Sitar was the Vice President of Finance for Vital Signs, Inc., a publicly traded manufacturer and distributor of single use medical products. From June 1993 to April 1996, Mr. Sitar was the Controller of Zenith. From 1982 through July 1993, he was with Coopers & Lybrand, a public accounting firm. He holds a B.S. in accounting from the University of Scranton and is licensed as a Certified Public Accountant in New Jersey.

Audit Committee

We have a separately designated standing audit committee established in accordance with section 3(a)(58)(A) of the Exchange Act. Our audit committee consists of Anthony E. Maida, III, Ph.D., M.A., M.B.A., Lorin K. Johnson, Ph.D., and Saira Ramasastry, M.A., M. Phil. The chair of our audit committee is Dr. Maida. The Board has determined that Dr. Maida is an "audit committee financial expert," as that term is defined by the SEC rules implementing Section 407 of the Sarbanes-Oxley Act, and possesses financial sophistication, as defined under applicable Nasdaq rules. The Board has also determined that each member of our audit committee can read and understand fundamental financial statements in accordance with applicable SEC and Nasdaq rules. To arrive at these determinations, the Board has examined each audit committee member's scope of experience and the nature of his or her experience in the corporate finance sector.

Code of Ethics and Business Conduct

We have adopted a Code of Ethics and Business 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 Ethics and Business 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. 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 standard, concerning any amendment to, or waiver from, our Code of Ethics and Business 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 proxy statement.

Item 11. Executive Compensation.

The following table provides information regarding the compensation of our named executive officers during the years ended December 31, 2019 and 2018.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus[1] ($)	Stock Awards[2] ($)	Option Awards[3] ($)	Non-equity Incentive Plan Compensation[4] ($)	All Other Compensation ($)	Total ($)
Sandeep Laumas, M.D.	2019	$ 275,000	$ —	$ —	$ 200,152	$ —	$ —	$ 475,152
Chief Executive Officer and Executive Chairman[5]	2018	$ 256,250	$ 96,250	$ —	$ —	$ 335,000	$ —	$ 687,500
Christopher Prior, Ph.D.	2019	$ 49,617	$ —	$ —	$ —	$ —	$ 259,039	$ 308,656
Chief Executive Officer[6]	2018	$ 295,000	$ —	$ —	$ —	$ 310,000	$ —	$ 605,000
Jay P. Madan, M.S.	2019	$ 285,000	$ —	$ —	$ 100,076	$ —	$ —	$ 385,076
President and Chief Business Officer	2018	$ 273,333	$ 99,750	$ —	$ —	$ 315,000	$ —	$ 688,083
Patrick Griffin, M.D., F.A.C.P.	2019	$ 388,125	$ 125,000	$ 183,375	$ 448,441	$ —	$ —	$ 1,144,941
Chief Medical Officer[7]	2018	$ —	$ —	$ —	$ —	$ —	$ —	$ —

(1) During March 2019, the compensation committee awarded cash bonuses to certain executives and senior employees for 2018 performance (the "2018 Bonus"). The 2018 Bonus was determined as a percentage of the executive's annual base salary. The compensation committee has not awarded performance bonuses for 2019 to date. See section entitled "Employment Agreements with Our Named Executive Officers" below for further details of discretionary bonuses awarded.

(2) The amount in the "Stock Awards" column reflects the grant date fair value of restricted stock units granted during the calendar year computed in accordance with the provisions of Accounting Standards Codification ("ASC") 718, Compensation-Stock Compensation. The grant date fair value, which is based on the value of the underlying common stock on the date of grant, does not reflect the actual economic value that will be realized by Dr. Griffin upon the vesting of the restricted stock units or the sale of the common stock underlying the award.

(3) The amounts in the "Option Awards" column reflect the aggregate Black-Scholes grant date fair value of stock options granted during the calendar year computed in accordance with the provisions of ASC 718, Compensation-Stock Compensation. The assumptions that were used to calculate the value of these awards are discussed in Notes 1 and 9 to the accompanying financial statements included in this Annual Report on Form 10-K. 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.

(4) As described below under the heading "Employment Agreements," pursuant to the terms of each executive officer's employment agreement with Private Innovate, further amended upon completion of the Monster Merger, bonus payments would be made if Private Innovate reached specific financial milestones prior to March 15, 2018. Amounts reflected for 2018 represent bonus payments awarded for achievement of milestones 2 and 3 related to 2018 performance. In addition, amounts reflected for 2018 include bonuses paid to Dr. Laumas, Dr. Prior and Mr. Madan of $50,000, $10,000 and $50,000, respectively, in connection with the completion of the Monster Merger.

(5) Dr. Laumas was appointed as Chief Executive Officer effective February 19, 2019 and has served as our Executive Chairman since the closing of the Monster Merger.

(6) Dr. Prior resigned as Chief Executive Officer effective February 19, 2019. Other compensation represents severance payments to Dr. Prior in accordance with his employment agreement.

(7) Dr. Griffin was appointed as Chief Medical Officer effective February 16, 2019. Prior to his appointment as Chief Medical Officer, Dr. Griffin received $60,000 of consulting fees for his service as a consultant during January and February 2019 and these fees are included in salary. Dr. Griffin also received consulting fees of $31,000 for consulting services during 2018 that are not included in the table above. Dr. Griffin received a $50,000 bonus upon termination of his consulting agreement and a discretionary bonus of $75,000 upon dosing of the first patient in our Phase 3 clinical trial for celiac disease.

Narrative Disclosure to Summary Compensation Table

The primary elements of compensation for our named executive officers consisted of base salary, annual performance bonus, equity-based compensation awards and other compensation such as discretionary bonuses and milestone-based bonuses. Our named executive officers were also able to participate in employee benefit plans and programs that we offer to our other full-time employees on the same basis. Each of our named executive officers is (or was) compensated by us pursuant to an executive employment agreement, the terms of which are described below under "Employment Agreements with Our Named Executive Officers."

Base Salary

The base salary payable to our 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 we did not have a written bonus plan, the Board had the authority, in its discretion, to award bonuses to its executive officers on a case-by-case basis. The 2018 awards were granted as a percentage of the executive's base salaries to reward the executive officers for company and individual success in 2018. The compensation committee has not awarded performance bonuses for 2019 to date.

Equity Awards

We currently have two equity incentive plans, the 2015 Stock Incentive Plan and the 2012 Omnibus Incentive Plan, as amended. In conjunction with the Monster Merger, we adopted the 2012 Omnibus Incentive Plan, as amended, and will no longer award options under the 2015 Stock Incentive Plan. For information about stock option awards granted to our named executive officers, see the "Outstanding Equity Awards at Year-end" table below. We believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention by incentivizing executives to continue employment during the vesting period.

Health, Welfare and Additional Benefits

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

2019 Outstanding Equity Awards at Fiscal Year-End

The following table presents the outstanding equity awards held by our named executive officers as of December 31, 2019.

	Option Awards					Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable		Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested (#)	Market Value of Shares or Units of Stock that Have Not Vested ($)
Sandeep Laumas, M.D.	86,679	(1)	26,380	$ 2.08	3/20/2027	—	$ —
	80,450	(2)	19,419	$ 2.34	8/29/2027	—	$ —
	162,500	(3)	237,500	$ 0.89	8/19/2029	—	$ —
Christopher Prior, Ph.D.	1,356,717	(4)	—	$ 0.30	11/1/2025	—	$ —
	578,358	(5)	—	$ 0.30	11/1/2025	—	$ —
	86,679	(6)	26,380	$ 2.08	3/20/2027	—	$ —
	60,717	(2)	14,656	$ 2.34	8/29/2027	—	$ —
Jay P. Madan, M.S.	86,679	(6)	26,380	$ 2.08	3/20/2027	—	$ —
	72,860	(2)	17,587	$ 2.34	8/29/2027	—	$ —
	81,250	(3)	118,750	$ 0.89	8/19/2029	—	$ —
Patrick Griffin, M.D., F.A.C.P.	203,125	(7)	296,875	$ 1.65	5/16/2029	12,500	$ 7,000

(1) This option was granted under the Private Innovate Plan and vests monthly over four years, with the first installment vesting on February 28, 2017.

(2) This option was granted under the Private Innovate Plan and vests monthly over three years, with the first installment vesting on July 1, 2017.

(3) This option was granted under the Omnibus Plan, and 25% of these options vested on February 19, 2019, with the remainder vesting monthly over the next 48 months.

(4) This option was granted under the Private Innovate Plan and vested immediately on the date of grant.

(5) This option was granted under the Private Innovate Plan, and 25% of these shares vested on November 2, 2015, with the remainder vesting monthly over the next 48 months.

(6) This option was granted under the Private Innovate Plan, and 20% of these shares vested on March 21, 2017, with the remainder vesting monthly over the next 48 months.

(7) This option was granted under the Omnibus Plan and 25% of the option shares vested on February 15, 2019, with the remainder vesting monthly over the next 48 months. These restricted stock units were granted under the Omnibus Plan, and 25% vested on February 15, 2019, with the remainder vesting monthly beginning February 15, 2019 over the next 12 months.

Employment Agreements with Our Named Executive Officers

Sandeep Laumas, M.D.

Private Innovate entered into an executive employment agreement with Dr. Laumas in October 2015, as amended, which included provisions with respect to, among other things, base salary and financial milestone events. Upon the occurrence of the Second and Third Financial Milestone Events under the agreement, Dr. Laumas's annual base salary was increased to $160,000 and $175,000, respectively, and Dr. Laumas became entitled to receive one-time lump sum cash bonuses in the amount of $110,000 and $175,000, respectively. Effective with the consummation of the equity financing completed in January 2018 (the "Equity Issuance"), the Second and Third Financial Milestone Events were achieved, and the cash bonuses were paid to Dr. Laumas in 2018.

On March 11, 2018, we entered into an amended and restated executive employment agreement with Dr. Laumas. Under this amended and restated executive employment agreement, Dr. Laumas is entitled to receive an annual base salary of $275,000,

subject to periodic increase as we may determine, and is generally eligible to participate in employee benefit and bonus programs established by us from time to time that may be applicable to our executives. If we terminate the executive employment agreement other than "for cause," or if Dr. Laumas terminates the executive employment agreement for "Good Reason," then Dr. Laumas is entitled to receive 12 months of his then-current base salary and up to 12 months of continuation of health insurance benefits, provided that he executes and does not revoke a release and settlement agreement in a form satisfactory to us.

On February 18, 2019, the Board appointed Dr. Laumas to the additional position of Chief Executive Officer, effective upon the resignation of Dr. Prior (as described below). Dr. Laumas is not entitled to any additional compensation as a result of his appointment as our Chief Executive Officer. In connection with this appointment, we entered into an amendment to Dr. Laumas's amended and restated executive employment agreement that provides that any subsequent cessation of Dr. Laumas's status as Chief Executive Officer will not constitute "Good Reason" under his executive employment agreement.

Christopher P. Prior, Ph.D.

Private Innovate entered into an executive employment agreement with Dr. Prior in November 2015, as amended, which included provisions with respect to, among other things base salary and financial milestone events. Upon the occurrence of the Second and Third Financial Milestone Events under the agreement, Dr. Prior's annual base salary increased to $260,000 and $300,000, respectively, and Dr. Prior became entitled to one-time lump sum cash bonuses in the amount of $125,000 and $175,000, respectively. Effective with the consummation of the Equity Issuance, the Second and Third Financial Milestone Events were achieved, and the cash bonuses were paid to Dr. Prior in 2018.

On March 11, 2018, we entered into an amended and restated executive employment agreement with Dr. Prior. Under this amended and restated executive employment agreement, Dr. Prior became entitled to receive an annual base salary of $300,000, subject to periodic increase as determined by us, and became generally eligible to participate in employee benefit and bonus programs established by us from time to time that may be applicable to our executives.

On February 18, 2019, Dr. Prior resigned as our Chief Executive Officer and as a director, effective February 19, 2019. In connection with Dr. Prior's resignation, we entered into a separation and release agreement with Dr. Prior pursuant to which Dr. Prior became entitled to the severance payments set forth in his amended and restated executive employment agreement, including an amount equal to 12 months of his current base salary and certain health care reimbursement benefits, and, additionally, continued vesting of his outstanding time-based equity awards for the 12-month period following the separation. On February 19, 2019, we also entered into a consulting agreement with Dr. Prior pursuant to which he was required to provide advisory services as requested by us for a 12-month term at a rate of $350 per hour. We did not make any payments to Dr. Prior under his consulting agreement.

Jay P. Madan, M.S.

Private Innovate entered into an executive employment agreement with Mr. Madan in October 2015, as amended, which included provisions with respect to, among other things, base salary and financial milestone events. Upon the occurrence of the Second and Third Financial Milestone Events under the agreement, Mr. Madan's annual base salary increased to $210,000 and $250,000, respectively, and Mr. Madan became entitled to receive one-time lump sum cash bonuses in the amount of $115,000 and $150,000, respectively. Effective with the consummation of the Equity Issuance, the Second and Third Financial Milestone Events were achieved, and the cash bonuses were paid to Mr. Madan in 2018.

On March 11, 2018, we entered into amended and restated executive employment agreement with Mr. Madan. Under this amended and restated executive employment agreement, Mr. Madan is entitled to receive an annual base salary of $285,000, subject to periodic increase as we may determine, and is generally eligible to participate in employee benefit and bonus programs established by us from time to time that may be applicable to our executives. If we terminate the amended and restated executive employment agreement other than "for cause," or if Mr. Madan terminates the agreement for "Good Reason," then Mr. Madan is entitled to receive 12 months of his then-current base salary and up to 12 months of continuation of health insurance benefits, provided that he executes and does not revoke a release and settlement agreement in a form satisfactory to us.

Patrick Griffin, M.D., F.A.C.P.

Dr. Griffin was appointed as Chief Medical Officer effective February 15, 2019, and provided consulting services as head of clinical development from November 2018 until February 2019. The Company entered into an executive employment agreement with Dr. Griffin in February 2019.

Pursuant to the executive employment agreement with Dr. Griffin, Dr. Griffin receives an annual base salary of $375,000 and received a performance bonus of $75,000 upon dosing the first patient in our Phase 3 clinical trial in celiac disease. Dr. Griffin is also generally eligible to participate in employee benefit and bonus programs established by us from time to time that may be applicable to our executives, with a target bonus opportunity of between 25% and 50% of his base salary.

Dr. Griffin received an initial grant of options to purchase 500,000 shares of our common stock, with 25% vesting on the date of grant and the remainder vesting over four years. In addition, Dr. Griffin received an initial grant of 100,000 restricted stock units, with 25% vesting immediately on the date of grant and the remainder vesting over one year.

If we terminate Dr. Griffin's executive employment agreement for any reason other than "for cause," or if Dr. Griffin terminates his executive employment agreement for "Good Reason," then Dr. Griffin is entitled to receive 12 months of his then-current base salary and up to 12 months of continuation of health insurance benefits, provided that Dr. Griffin executes and does not revoke a release and settlement agreement in a form satisfactory to us. Dr. Griffin is also entitled to receive his annual bonus for the year of termination as determined by the Board, pro-rated based on the number of days Dr. Griffin was employed during the year of termination.

2019 Director Compensation

The following table provides compensation information regarding our non-employee directors for the year ended December 31, 2019.

Name	Fees Earned or Paid in Cash [1] ($)	Option Awards [2] ($)	Total ($)
Lorin K. Johnson, Ph.D.	70,000	18,913	88,913
Roy Proujansky, M.D.	40,000	18,913	58,913
Anthony E. Maida III, Ph.D., M.A., M.B.A.	80,000	18,913	98,913
Saira Ramasastry, M.S., M. Phil.	70,000	18,913	88,913

(1) Fees earned or paid in cash reflect the non-employee director compensation earned or paid in cash during the year ended December 31, 2019.

(2) The amounts in the "Option Awards" column reflect the aggregate Black-Scholes grant date fair value of stock options granted during the calendar year computed in accordance with the provisions of ASC 718, Compensation-Stock Compensation. The assumptions that were used to calculate the value of these awards are discussed in Notes 1 and 9 to the accompanying financial statements included in this Annual Report on Form 10-K. These amounts do not reflect the actual economic value that will be realized by the directors upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such stock options.

The table below shows the aggregate number of option awards held as of December 31, 2019 by each of our current non-employee directors who was serving as of that date.

Name	Options Outstanding as of December 31, 2019
Lorin K. Johnson, Ph.D.	351,492
Roy Proujansky, M.D.	100,000
Anthony E. Maida III, Ph.D., M.A., M.B.A.	163,059
Saira Ramasastry, M.S., M. Phil.	100,000

Non-Employee Director Compensation Policy

On September 21, 2018, we adopted a policy with respect to compensation of our non-employee directors, the Non-Employee Director Compensation Policy. Each non-employee director is eligible to receive annual cash and equity compensation for his or her service without further action by the Board, subject to continued service on the Board. Our non-employee directors receive the following annual retainers:

Position	Retainer
Board member	$ 40,000
Chairman of the Board	35,000
Audit Committee Chair	25,000
Audit Committee member	7,500
Compensation Committee Chair	15,000
Compensation Committee member	7,500
Nominating and Corporate Governance Chair	15,000
Nominating and Corporate Governance member	7,500

In addition, each non-employee director who serves on the Board as of the date of any annual meeting of our stockholders (the "Annual Meeting") will automatically be granted on the date of such Annual Meeting, options to purchase 25,000 shares of our common stock. The annual equity awards will vest monthly over a period of three years, subject to continued service on the Board. 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 the Annual Meeting will automatically be granted options to purchase 50,000 shares of our common stock. 10% of the underlying shares will vest immediately on the date of grant, with the remainder of shares vesting over 36 equal monthly installments.

Directors may be reimbursed for travel, food, lodging and other expenses directly related to their service as directors. Directors are also entitled to the protection provided by their indemnification agreements and the indemnification provisions in our certificate of incorporation and by-laws.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

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 common stock as of March 17, 2020, (except where otherwise indicated) by:

- 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;
- each of our directors;
- each of our named executive officers; and
- all of our current directors and executive officers as a group.

Beneficial ownership is determined in accordance with SEC rules 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 17, 2020, 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[1]
Principal Stockholders:		
Moonstar Family Group [2]	2,688,217	6.5 %
The Sea Island Partnership [3]	2,892,298	7.0 %
Directors and Named Executive Officers:		
Christopher Prior, Ph.D. [4]	2,095,552	4.8 %
Jay P. Madan, M.S. [5]	1,303,424	3.1 %
Sandeep Laumas, M.D. [6]	1,139,410	2.7 %
Patrick Griffin, M.D., F.A.C.P. [7]	342,188	*
Lorin K. Johnson, Ph.D. [8]	302,094	*
Anthony E. Maida III, Ph.D., M.A., M.B.A. [9]	113,661	*
Roy Proujansky, M.D. [10]	59,345	*
Saira Ramasastry, M.S., M. Phil. [11]	51,945	*
All directors and executive officers as a group (8 persons) [12]	3,338,317	7.8 %

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

(1) The percentage of beneficial ownership is based on 41,324,976 shares of common stock outstanding as of March 17, 2020.

(2) Consists of 2,688,217 shares of common stock held by Moonstar Family Group. The managing member of Moonstar Family Group is Chris Durant.

(3) Consists of 2,892,298 shares of common stock held by The Sea Island Partnership. The manager of The Sea Island Partnership is Michael Huter.

(4) Consists of (i) 7,009 shares of common stock held by Dr. Prior and (ii) options to purchase 2,088,543 shares of common stock held by Dr. Prior that are exercisable within 60 days of March 17, 2020.

(5) Consists of (i) 84,131 shares of common stock held by Mr. Madan, (ii) 129,593 shares of common stock held by Madan Global, Inc., (iii) 122,104 shares of common stock held by OM Healthcare Partners LLC, (iv) 122,104 shares of common stock held by OM Healthcare Partners II LLC, (v) 122,104 shares of common stock held by OM Healthcare Partners III LLC, (vi) 450,000 shares of common stock held by MGI Holdings II LLC and (vii) options to purchase 273,388 shares of common stock held by Mr. Madan that are exercisable within 60 days of March 17, 2020. Mr. Madan is affiliated with Madan Global, Inc., MGI Holdings II LLC and with each of the named OM Healthcare Partners companies, and has voting and investment power over these shares. Mr. Madan disclaims beneficial ownership of the shares of Madan Global, Inc., MGI Holdings II LLC and the OM Healthcare Partners companies except to the extent of his pecuniary interest therein.

(6) Consists of (i) 14,000 shares of common stock held by Dr. Laumas, (ii) 758,373 shares held by Bearing Circle Capital LLC and (iii) options to purchase 367,037 shares of common stock held by Dr. Laumas that are exercisable within 60 days of March 17, 2020. Dr. Laumas is affiliated with Bearing Circle Capital and has voting and investment power over the shares held by Bearing Circle Capital. Dr. Laumas disclaims beneficial ownership of the shares held by Bearing Circle Capital LLC except to the extent of his pecuniary interest therein.

(7) Consists of 100,000 shares of common stock held by Dr. Griffin and options to purchase 242,188 shares of common stock held by Dr. Griffin that are exercisable within 60 days of March 17, 2020.

(8) Consists of options to purchase 302,094 shares of common stock held by Dr. Johnson that are exercisable within 60 days of March 17, 2020.

(9) Consists of options to purchase 113,661 shares of common stock held by Dr. Maida that are exercisable within 60 days of March 17, 2020.

(10) Consists of (i) 2,400 shares of common stock held by Dr. Proujansky and (ii) options to purchase 56,945 shares of common stock held by Dr. Proujansky that are exercisable within 60 days of March 17, 2020.

(11) Consists of options to purchase 51,945 shares of common stock held by Ms. Ramasastry that are exercisable within 60 days of March 17, 2020.

(12) Includes 3,338,317 shares owned or issuable upon the exercise of options held by the Company’s current directors and executive officers that are exercisable within 60 days of March 17, 2020.

Equity Compensation Plan Information

The following table provides aggregate information as of December 31, 2019, with respect to compensation plans under which shares of our common stock may be issued.

Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options (a)	Weighted-Average Exercise Price of Outstanding Options (b)	Number of Securities Remaining Available for Future Issuances under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders [1]	8,781,615	$ 1.64	1,102,739
Equity compensation plans not approved by security holders	—	—	—
Total	8,781,615	$ 1.64	1,102,739

(1) Consists of (i) 6,063,745 shares of common stock issuable upon exercise of outstanding options under the Private Innovate Plan and (ii) 2,717,870 shares of common stock issuable upon exercise of outstanding options under the Omnibus Plan. Securities available for future issuances include 1,102,739 shares remaining for future issuance under the Omnibus Plan.

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

Related Person Transaction Policy and Procedures

The 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, in which 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.

Certain Related Person Transactions

Described below is each transaction occurring since January 1, 2018, and any currently proposed transaction to which we were or are to be a participant, respectively, and in which:

- The amounts involved exceeded or will exceed 1% of the average of our total assets at year-end for the last two completed fiscal years; and

- Any person (i) who since January 1, 2018 served as a director or executive officer of the Company or any member of such person's immediate family that 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" or (ii) who, at the time when a transaction in which such person had a direct or indirect material interest occurred or existed, was a beneficial owner of more than 5% of our outstanding common stock or any member of such person's immediate family.

Each of these transactions was approved pursuant to our related transaction policy.

Equity Financing:

Pursuant to a securities purchase agreement (the "Purchase Agreement") with SDS Capital Partners II, LLC and certain other accredited investors, in March 2019, we issued an aggregate of 4,181,068 shares of common stock at a price of $2.33 per

share. In a concurrent private placement, we issued warrants to purchase 6,689,702 shares of common stock, of which 4,181,068 are exercisable immediately.

Of the shares and warrants issued in March 2019, 50,000 shares of common stock and warrants to purchase 80,000 shares of common stock were issued to GSB Holdings, Inc., a family-owned company of David Clarke, who previously served as Chief Executive Officer and Chairman of the Board of the Company prior to the Monster Merger. The aggregate purchase price of the common stock shares issued to GSB Holdings, Inc. was $116,500. In addition, warrants to purchase 50,000 shares of common stock are exercisable immediately, have an expiration date of September 18, 2020 and have an exercise price of $4.00. Warrants to purchase 30,000 shares of common stock became exercisable on the six-month anniversary of March 18, 2019, have an expiration date of March 18, 2024, and have an exercise price of $2.56.

In April 2019, we entered into an amendment to the Purchase Agreement, between us and each purchaser, including GSB Holdings, Inc. (the "Amendment"). The Amendment gave each purchaser the right to purchase, for $0.125 per underlying share, an additional warrant to purchase shares of our common stock having an exercise price per share of $2.13 and otherwise having the terms of the long-term warrants issued in the March 2019 transaction (collectively, the "New Warrants") pursuant to a securities purchase agreement (the "New Securities Purchase Agreement") entered into among us and each purchaser on May 17, 2019.

We issued New Warrants exercisable for an aggregate of 3,897,010 shares of our common stock and the New Warrants are exercisable for five years beginning on the six-month anniversary of the date of issuance. The New Warrants have an initial exercise price equal to $2.13 per share, subject to certain adjustments. Pursuant to the New Securities Purchase Agreement, GSB Holdings, Inc. received New Warrants to purchase an additional 46,638 shares of our common stock.

Employment and Consulting Agreements with Our Named Executive Officers:

We have entered into employment agreements with each of our named executive officers. In addition, prior to his service as our Chief Medical Officer and at a time when he was not a related person of the Company, we entered into a consulting agreement with Dr. Griffin, and subsequent to his service as our Chief Executive Officer, we entered into a consulting agreement with Dr. Prior. These arrangements are described above under "Executive Compensation-Summary Compensation Table" and "Executive Compensation-Summary Compensation Table-Employment Agreements with Our Named Executive Officers" in Part III, Item 11 of this report.

Independence of Directors

Our common stock is listed on The Nasdaq Capital Market. Under Nasdaq rules, independent directors must comprise a majority of the Board, and each member of our audit committee, compensation committee and nominating and corporate governance committee must be independent. Under Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with such person's exercise of independent judgment in carrying out the responsibilities of a director.

Audit committee members must also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. To be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of a company's audit committee, the company's board of directors or any other board committee, (i) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (ii) be an affiliated person of the listed company or any of its subsidiaries.

The Board has undertaken a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, the Board has determined that each of Lorin K. Johnson, Ph.D., Anthony E. Maida, III, Ph.D., M.A., M.B.A., Roy Proujansky, M.D., and Saira Ramasastry, M.S., M. Phil., does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under applicable Nasdaq rules. In making these determinations, the Board considered the current and prior relationships that each non-employee director has with us and all other facts and circumstances the Board deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director.

The Board also determined that each of Anthony E. Maida, III, Ph.D., M.A., M.B.A., Lorin K. Johnson, Ph.D. and Saira Ramasastry, M.S., M. Phil., the three members of our audit committee, satisfies the independence standards for the audit committee established by applicable Nasdaq rules and SEC Rule 10A-3.

The Board has determined that each of Saira Ramasastry, M.S., M. Phil., Lorin K. Johnson, Ph.D. and Anthony E. Maida III, Ph.D., M.A., M.B.A., the three current members of each of our compensation committee and our nominating and corporate governance committee, is independent within the meaning of applicable Nasdaq rules.

Item 14. Principal Accountant Fees and Services.

Substantially all of Mayer Hoffman McCann P.C. ("MHM") personnel, who work under the control of MHM shareholders, are employees of wholly-owned subsidiaries of CBIZ, Inc., which provides personnel and various services to MHM in an alternative practice structure. The following table represents aggregate fees billed to the Company, by MHM, the Company's independent registered public accounting firm for the fiscal years ended December 31, 2019 and 2018.

	Fiscal Year Ended	
	2019	2018
	(in thousands)	
Audit Fees [1]	$ 253	$ 347
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$ 253	$ 347

(1) Audit fees consist of fees billed for the professional services rendered to the Company for the audit of the Company's annual financial statements for the years ended December 31, 2019 and 2018, reviews of the quarterly financial statements during the periods, the issuance of consent and comfort letters in connection with registration statement filings, and all other services that are normally provided by the accounting firm in connection with statutory and regulatory filings and engagements.

All fees described above were approved by our audit committee.

Pre-Approval Policies and Procedures

Our audit committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by the Company's independent registered public accounting firm. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services and tax services up to specified amounts. Pre-approval may also be given as part of our audit committee's approval of the scope of the engagement of the independent auditor or on an individual, explicit, case-by-case basis before the independent auditor is engaged to provide each service. The pre-approval of services may be delegated to one or more of our audit committee's members, but the decision must be reported to the full audit committee at its next scheduled meeting.

Our audit committee has determined that the rendering of services other than audit services by MHM to date are compatible with maintaining the principal accountant's independence.

PART IV

Item 15. Exhibits and 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

				INCORPORATED BY REFERENCE		
EXHIBIT NO.		**DESCRIPTION**	**FILED HEREWITH**	**FORM**	**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	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	2.1	January 5, 2018
2.3	+	Agreement and Plan of Merger and Reorganization, dated October 6, 2019, by and among the Company, INNT Merger Sub 1 Ltd., RDD Pharma Ltd., and Orbimed Israel Partners, Limited Partnership		8-K	2.1	October 7, 2019
2.4	+	First Amendment to Agreement and Plan of Merger and Reorganization, dated December 17, 2019, by and among the Company, INNT Merger Sub 1 Ltd., RDD Pharma Ltd., and Orbimed Israel Partners, Limited Partnership		8-K	2.1	December 17, 2019
3.1		Amended and Restated Certificate of Incorporation of the Company		10-K	3.1	March 18, 2019
3.2		Amended and Restated Bylaws of the Company		8-K	3.1	December 10, 2018
4.1		Form of Share Certificate		10-K	4.1	March 14, 2018
4.2		Description of the Company's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934	X			
4.3		Form of Warrant		8-K	4.1	February 2, 2018
4.4		Subscription Agreement dated January 29, 2018		8-K	10.1	February 2, 2018

EXHIBIT NO.		DESCRIPTION	FILED HEREWITH	INCORPORATED BY REFERENCE		
				FORM	EXHIBIT	FILING DATE
4.5		Form of Warrant Certificate		S-1/A	4.2	June 24, 2016
4.6		Form of Warrant Agreement by and between Monster Digital, Inc. and Corporate Stock Transfer, Inc.		S-1/A	4.3	June 24, 2016
4.7		Convertible Promissory Note, dated March 8, 2019, by and between the Company and Atlas Sciences, LLC		8-K	4.1	March 13, 2019
4.8		Form of Long-Term Warrant		8-K	4.1	March 18, 2019
4.9		Form of Short-Term Warrant		8-K	4.2	March 18, 2019
4.10		Form of Common Stock Purchase Warrant		8-K	4.1	May 1, 2019
4.11		Form of Placement Agent Warrant		8-K	4.2	May 1, 2019
4.12		Form of New Warrant (included in Exhibit 10.5)		8-K	4.1	May 17, 2019
10.1	†	Sublicense Agreement, dated February 19, 2016, between the Company and Alba Therapeutics Corporation		10-K/A	10.1	June 29, 2018
10.2	†	License Agreement, dated February 26, 2016, by and between the Company and Alba Therapeutics Corporation		10-K/A	10.2	June 29, 2018
10.3	†	Asset Purchase Agreement, dated December 23, 2014, by and between the Company and Repligen Corporation		10-K	10.3	March 14, 2018
10.4	†	Apaza License Agreement, dated April 19, 2013, by and between the Company and Seachaid Pharmaceuticals, Inc., as amended		10-K	10.4	March 14, 2018
10.5	†	Master Services Agreement dated August 20, 2018, by and between the Company and Amarex Clinical Research, LLC		10-Q	10.1	November 13, 2018
10.6	#	Form of Director Indemnification Agreement		8-K	10.3	February 2, 2018
10.7	#	2012 Innovate Omnibus Incentive Plan, as amended		8-K	10.1	December 10, 2018
10.8	#	Form of Option Agreement and Option Grant Notice under the 2012 Omnibus Incentive Plan		S-1	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	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	10.4	November 10, 2015
10.11	#	Innovate Biopharmaceuticals Inc. 2015 Stock Incentive Plan, as amended		10-K	10.11	March 14, 2018
10.12	#	Form of Incentive Stock Option Agreement under the 2015 Stock Incentive Plan		10-K	10.12	March 14, 2018

EXHIBIT NO.		DESCRIPTION	FILED HEREWITH	INCORPORATED BY REFERENCE		
				FORM	EXHIBIT	FILING DATE
10.13	#	Form of Nonstatutory Stock Option Agreement under the 2015 Stock Incentive Plan		10-K	10.13	March 14, 2018
10.14	#	Form of Restricted Stock Purchase Agreement under the 2015 Stock Incentive Plan		10-K	10.14	March 14, 2018
10.15	#	Non-Employee Director Compensation Policy dated September 21, 2018		10-Q	10.2	November 13, 2018
10.16	#	Amended and Restated Executive Employment Agreement, dated March 11, 2018, by and between the Company and Sandeep Laumas		10-K	10.25	March 14, 2018
10.17	#	First Amendment, dated February 19, 2019, to Amended and Restated Executive Employment Agreement, dated March 11, 2018, by and between the Company and Sandeep Laumas		10-K	10.27	March 18, 2019
10.18	#	Amended and Restated Executive Employment Agreement, dated March 11, 2018, by and between the Company and Christopher Prior		10-K	10.26	March 14, 2018
10.19	#	Separation Agreement, dated February 19, 2019, by and between the Company and Christopher Prior		10-K	10.29	March 18, 2019
10.20	#	Consulting Agreement, dated February 19, 2019, by and between the Company and Christopher Prior		10-K	10.30	March 18, 2019
10.21	#	Amended and Restated Executive Employment Agreement, dated March 11, 2018, by and between the Company and Jay Madan		10-K	10.27	March 14, 2018
10.22	#	Executive Employment Agreement dated June 22, 2019, by and between the Company and Edward J. Sitar		8-K	10.1	June 27, 2019
10.23	#	Executive Employment Agreement dated February 15, 2019, by and between the Company and Patrick H. Griffin, M.D.	X			
10.24		Common Stock Sales Agreement, dated October 26, 2018, by and among the Company and H.C. Wainwright & Co., LLC and Ladenburg Thalmann & Co. Inc.		8-K	10.1	October 29, 2018
10.25		Convertible Promissory Note, dated March 8, 2019, by and between the Company and Atlas Sciences, LLC		8-K	4.1	March 13, 2019
10.26		Securities Purchase Agreement, dated March 8, 2019, by and between the Company and Atlas Sciences, LLC		8-K	10.1	March 13, 2019
10.27		Securities Purchase Agreement, dated March 17, 2019, by and among the Company and the purchasers party thereto		8-K	10.1	March 18, 2019
10.28		Amendment to Securities Purchase Agreement, dated April 25, 2019, by and among the Company and the purchasers party thereto		8-K	10.1	April 26, 2019
10.29		Securities Purchase Agreement, dated April 29, 2019, by and among the Company and the purchasers party thereto		8-K	10.1	May 1, 2019

EXHIBIT NO.	DESCRIPTION	FILED HEREWITH	INCORPORATED BY REFERENCE		
			FORM	EXHIBIT	FILING DATE
10.30	Engagement Letter, dated April 26, 2019, by and between the Company and H.C. Wainwright & Co., LLC		8-K	10.2	May 1, 2019
10.31	Securities Purchase Agreement, dated May 17, 2019, by and among the Company and the purchasers party thereto (included in Amendment, dated April 25, 2019, to Securities Purchase Agreement, dated March 17, 2019, among the Company and the purchasers party thereto, filed as Exhibit 10.1 to Form 8-K filed on April 26, 2019 and incorporated by reference herein)		8-K	10.1	April 26, 2019
10.32	Form of Stockholder Support Agreement by and among the Company, RDD Pharma Ltd., and certain stockholders of the Company		8-K	10.1	October 7, 2019
10.33	Form of Lock-Up Agreement		8-K	10.2	October 7, 2019
10.34	Form of Exchange Agreement		8-K	10.1	December 20, 2019
10.35	Option to Purchase Senior Convertible Note, dated January 7, 2019, by and between the Company and Gustavia Capital Partners LLC and/or its affiliates		8-K	10.1	January 11, 2019
23.1	Consent of Mayer Hoffman McCann P.C.	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			
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 20, 2020

Innovate Biopharmaceuticals, Inc.

By: /s/ Sandeep Laumas
Name: Sandeep Laumas, M.D.
Title: Chief Executive Officer

Signature	Title	Date
/s/ Sandeep Laumas Sandeep Laumas, M.D.	Executive Chairman, Chief Executive Officer and Director (Principal Executive Officer)	March 20, 2020
/s/ Edward J. Sitar Edward J. Sitar	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 20, 2020
/s/ Jay P. Madan Jay P. Madan, M.S.	Director	March 20, 2020
/s/ Lorin K. Johnson Lorin K. Johnson, Ph.D.	Director	March 20, 2020
/s/ Anthony E. Maida III Anthony E. Maida III, Ph.D., M.A., M.B.A.	Director	March 20, 2020
/s/ Roy Proujansky Roy Proujansky, M.D.	Director	March 20, 2020
/s/ Saira Ramasastry Saira Ramasastry, M.S., M.Phil.	Director	March 20, 2020

INNOVATE BIOPHARMACEUTICALS, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Innovate Biopharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Innovate Biopharmaceuticals, Inc. (the “Company”) as of December 31, 2019 and 2018, and the related statements of operations and comprehensive loss, stockholders’ deficit, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred recurring negative cash flows from operations and is dependent on additional financing to fund operations. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are described in Note 2 to the financial statements. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Basis for Opinion

These 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 audits 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/ Mayer Hoffman McCann P.C.

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

Orange County, California
March 20, 2020

INNOVATE BIOPHARMACEUTICALS, INC.
BALANCE SHEETS

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 4,592,932	$ 5,728,900
Restricted deposit	75,000	75,000
Prepaid expenses and other current assets	555,052	504,907
Deferred offering costs	—	104,706
Total current assets	5,222,984	6,413,513
Property and equipment, net	25,422	35,095
Right-of-use asset	42,830	—
Other assets	5,580	5,580
Total assets	$ 5,296,816	$ 6,454,188
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 3,890,094	$ 3,618,634
Accrued expenses	4,747,751	826,327
Convertible note payable, net	3,184,655	5,196,667
Derivative liability	408,000	370,000
Warrant liabilities	2,637,500	—
Accrued interest	—	101,624
Lease liability, current portion	42,830	—
Total current liabilities	14,910,830	10,113,252
Commitments and contingencies (Note 11)		
Stockholders' deficit:		
Preferred stock $0.0001 par value as of December 31, 2019, 10,000,000 shares authorized as of December 31, 2019 and 2018; 0 shares issued and outstanding as of December 31, 2019 and 2018	—	—
Common stock $0.0001 par value as of December 31, 2019 and 2018, 350,000,000 shares authorized as of December 31, 2019 and 2018, 39,477,667 and 26,088,820 shares issued and outstanding as of December 31, 2019 and 2018, respectively	3,948	2,609
Additional paid-in capital	60,946,816	39,854,297
Accumulated deficit	(70,564,778)	(43,515,970)
Total stockholders' deficit	(9,614,014)	(3,659,064)
Total liabilities and stockholders' deficit	$ 5,296,816	$ 6,454,188

See accompanying notes to these financial statements.

INNOVATE BIOPHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 13,715,968	$ 7,559,077
General and administrative	10,566,813	10,664,991
Warrant inducement expense	1,265,780	—
Total operating expenses	25,548,561	18,224,068
Loss from operations	(25,548,561)	(18,224,068)
Other income (expense):		
Interest income	185,267	163,832
Interest expense	(1,825,148)	(6,152,043)
Loss on extinguishment of convertible note payable	(1,049,166)	—
Change in fair value of derivative liability and extinguishment of derivative liability	1,243,000	50,000
Change in fair value of warrant liabilities	(54,200)	—
Total other income (expense), net	(1,500,247)	(5,938,211)
Loss before income taxes	(27,048,808)	(24,162,279)
Benefit from income taxes	—	—
Net loss	$ (27,048,808)	$ (24,162,279)
Net loss per common share, basic and diluted	$ (0.81)	$ (0.98)
Weighted-average common shares, basic and diluted	33,328,591	24,762,151

See accompanying notes to these financial statements.

INNOVATE BIOPHARMACEUTICALS, INC.
STATEMENTS OF STOCKHOLDERS' DEFICIT

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance as of December 31, 2017	11,888,240	$ 11,888	$ 7,167,189	$ (19,353,691)	$ (12,174,614)
Change in par value from $0.001 to $0.0001	—	(10,699)	10,699	—	—
Issuance of shares as a result of reverse recapitalization	1,864,808	186	(978,860)	—	(978,674)
Issuance of common stock	7,129,207	713	16,181,289	—	16,182,002
Warrants issued with common stock	—	—	1,995,000	—	1,995,000
Warrants issued to placement agents	—	—	913,000	—	913,000
Stock issuance costs	—	—	(2,569,659)	—	(2,569,659)
Conversion of convertible debt and accrued interest	4,827,001	483	9,229,336	—	9,229,819
Beneficial conversion feature	—	—	3,077,887	—	3,077,887
Share-based compensation	—	—	3,805,000	—	3,805,000
Exercise of stock options	87,706	9	182,419	—	182,428
Exercise of warrants, net of issuance costs	291,858	29	840,997	—	841,026
Net loss	—	—	—	(24,162,279)	(24,162,279)
Balance as of December 31, 2018	26,088,820	$ 2,609	$ 39,854,297	$ (43,515,970)	$ (3,659,064)
Issuance of common stock	9,205,054	921	20,218,835	—	20,219,756
Allocation of warrants	—	—	(3,330,000)	—	(3,330,000)
Stock issuance costs	—	—	(709,442)	—	(709,442)
Share-based compensation	—	—	2,871,000	—	2,871,000
Exercise of stock options	100,079	10	30,054	—	30,064
Settlement of RSUs	490,000	49	(49)	—	—
Warrant exchange	3,593,714	359	2,012,121	—	2,012,480
Net loss	—	—	—	(27,048,808)	(27,048,808)
Balance as of December 31, 2019	39,477,667	$ 3,948	$ 60,946,816	$ (70,564,778)	$ (9,614,014)

See accompanying notes to these financial statements.

INNOVATE BIOPHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2019	**2018**
Cash flows from operating activities		
Net loss	$ (27,048,808)	$ (24,162,279)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	2,871,000	3,805,000
Write-off of deferred offering costs	100,056	—
Accrued interest on convertible notes	—	280,394
Amortization of debt discount	1,067,379	2,513,475
Depreciation	21,607	19,555
Beneficial conversion feature	—	3,077,887
Change in fair value of derivative liability	(873,000)	(50,000)
Change in fair value of warrant liabilities	54,200	—
Extinguishment of derivative liability	(370,000)	—
Warrant inducement expense	1,265,780	—
Loss on extinguishment of debt	1,049,166	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(50,145)	(298,724)
Accounts payable	124,973	86,412
Accrued expenses	3,921,424	(441,050)
Accrued interest	(101,624)	—
Net cash used in operating activities	(17,967,992)	(15,169,330)
Cash flows from investing activities		
Purchase of property and equipment	(11,934)	(13,943)
Purchase of restricted deposit	—	(75,000)
Loan payments from related party	—	75,000
Net cash used in investing activities	(11,934)	(13,943)
Cash flows from financing activities		
Borrowings from convertible notes	5,000,000	3,345,000
Payments of debt issuance costs	(57,000)	(50,000)
Payments of convertible notes	(7,790,557)	(275,000)
Proceeds from issuance of common stock and warrants	20,706,919	18,132,661
Proceeds from exercise of stock options	30,064	182,428
Proceeds from exercise of warrants	—	928,178
Payment of deferred offering costs	(1,045,468)	(1,706,657)
Net cash provided by financing activities	16,843,958	20,556,610
Net (decrease) increase in cash and cash equivalents	(1,135,968)	5,373,337
Cash and cash equivalents as of beginning of year	5,728,900	355,563
Cash and cash equivalents as of end of year	$ 4,592,932	$ 5,728,900
Supplemental disclosure of cash flow information		
Cash paid during the year for interest	$ 874,203	$ 280,287
Supplemental disclosure of non-cash financing activities		
Conversion of convertible notes and accrued interest to common stock	$ —	$ 9,229,819
Assumption of liabilities from reverse recapitalization transaction	$ —	$ 978,674
Warrants issued to placement agents	$ —	$ 913,000
Commissions payable in connection with exercise of warrants	$ —	$ 87,152
Accrued interest converted to convertible note payable	$ —	$ 156,667
Non-cash addition of derivative liability	$ 1,281,000	$ 420,000
Non-cash addition of deferred offering costs	$ 151,137	$ 54,706
Deferred offering costs reclassified to additional paid-in capital	$ —	$ 159,795

See accompanying notes to these financial statements.

NOTE 1: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Business Description

Innovate Biopharmaceuticals, Inc. (the "Company" or "Innovate") is a clinical-stage biopharmaceutical company developing novel medicines for autoimmune and inflammatory diseases with unmet medical needs. The Company's pipeline includes drug candidates for celiac disease, nonalcoholic steatohepatitis (NASH), alcoholic steatohepatitis (ASH), Crohn's disease and ulcerative colitis.

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 "Monster Merger Agreement"), by and among Monster, Monster Merger Sub, Inc. ("Monster Merger Sub") and Private Innovate. In connection with the transaction, Private Innovate changed its name to IB Pharmaceuticals Inc. ("IB Pharmaceuticals"). Pursuant to the Monster Merger Agreement, Monster Merger Sub merged with and into IB Pharmaceuticals with IB Pharmaceuticals surviving as the wholly owned subsidiary of Monster (the "Monster Merger"). Immediately following the Monster Merger, Monster changed its name to Innovate Biopharmaceuticals, Inc. ("Innovate"). On March 29, 2018, IB Pharmaceuticals was merged into Innovate and ceased to exist.

Monster, a Delaware corporation (formed in November 2010), and its subsidiary SDJ Technologies, Inc. ("SDJ"), was 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. In September 2017, Monster incorporated MD Holding Co, Inc. ("MDH"), a Delaware corporation, and transferred all of the businesses and assets of Monster, including all shares of SDJ and those liabilities of Monster not assumed by Innovate pursuant to the Monster Merger to MDH. In January 2018, the name of MDH was changed to NLM Holding Co., Inc.

On January 29, 2018, prior to the Monster Merger, Private Innovate completed an equity financing (the "Equity Issuance"). See Note 3—Monster Merger and Financing.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The Company's financial position, results of operations and cash flows are presented in U.S. Dollars.

Upon the closing of the Monster Merger, the outstanding shares of Private Innovate were exchanged for shares of common stock of Monster at an exchange ratio of one share of Private Innovate common stock to 0.37686604 shares of Monster common stock (the "Exchange Ratio"). All common share amounts and per share amounts have been adjusted to reflect this Exchange Ratio, which was effected upon the Monster Merger.

The Monster Merger has been accounted for as a reverse recapitalization. Prior to the Monster Merger, Monster spun-out all of its pre-merger business assets and liabilities before it acquired Private Innovate. The owners and management of Private Innovate have actual or effective voting and operating control of the combined company. In the Monster Merger transaction, Monster is the accounting acquiree and Private Innovate is the accounting acquirer. A reverse recapitalization is equivalent to the issuance of stock by the private operating company for the net monetary assets of the accounting acquiree accompanied by a recapitalization with accounting similar to that resulting from a reverse acquisition, except that no goodwill or intangible assets are recorded.

Immediately prior to the effective time of the Monster Merger, Monster effected a reverse stock split at a ratio of one new share for every ten shares of its common stock outstanding. In connection with the Monster Merger, 1,864,808 shares of the Company's common stock were transferred to the existing Monster stockholders and the Company assumed approximately $1.0 million in liabilities from Monster for certain transaction costs and tail insurance coverage for its directors and officers, which were recorded as a reduction of additional paid-in capital. In addition, warrants to purchase up to 154,403 shares of the Company's common stock remained outstanding after completion of the Monster Merger. These warrants have a weighted-average exercise price of $55.31 per share and expire in 2021 and 2022.

The accompanying financial statements and related notes reflect the historical results of Private Innovate prior to the Monster Merger and of the combined company following the Monster Merger, and do not include the historical results of Monster prior to the completion of the Monster Merger. These financial statements and related notes should be read in conjunction with the audited financial statements and related notes thereto for the year ended December 31, 2018, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on March 18, 2019.

Shelf Registration Filing

On March 15, 2018, the Company filed a shelf registration statement that was declared effective on July 13, 2018. Under the shelf registration statement, the Company may, from time to time, sell its common stock in one or more offerings up to an aggregate dollar amount of $175 million (of which up to an aggregate of $40 million may be sold in an "at-the-market" offering as defined in Rule 415 of the Securities Act; the use of this facility was voluntarily suspended on June 24, 2019 and subsequently terminated effective March 19, 2020). In addition, the selling stockholders included in the shelf registration statement may from time to time sell up to an aggregate amount of 13,990,403 shares of the Company's common stock (including up to 2,051,771 shares issuable upon exercise of warrants) in one or more offerings.

March 2019 Offering

On March 17, 2019, the Company entered into a securities purchase agreement (the "Purchase Agreement") with SDS Capital Partners II, LLC and certain other accredited investors, pursuant to which the Company sold, on March 18, 2019, 4,181,068 shares of common stock and issued short-term warrants (the "Short-Term Warrants") to purchase up to 4,181,068 shares of common stock, and long-term warrants (the "March Long-Term Warrants") to purchase up to 2,508,634 shares of common stock. Pursuant to the Purchase Agreement, the Company issued the common stock and warrants at a purchase price of $2.33 per share for aggregate proceeds of approximately $9.7 million.

The March Long-Term Warrants issued will be exercisable for 5 years commencing on the six-month anniversary of March 18, 2019, have an initial exercise price of $2.56 per share, subject to certain adjustments, and have an expiration date of March 18, 2024. Any March Long-Term Warrant that has not been exercised by the expiration date shall be automatically exercised via cashless exercise. The Short-Term Warrants were originally exercisable for a period of one year from March 18, 2019, had an expiration date of March 18, 2020 and had an initial exercise price of $4.00 per share, subject to certain adjustments. If at any time after March 18, 2019, the weighted-average price of the Company's common stock exceeds $5.25 for ten consecutive trading days, the Company may call the outstanding Short-Term Warrants and require that they be exercised in cash, except to the extent that such exercise would surpass the beneficial ownership limitations, as specified in the Purchase Agreement. If not previously exercised in full, at the expiration of their applicable terms, the warrants shall be automatically exercised via cashless exercise. The Short-Term Warrants and March Long-Term Warrants are classified as warrant liabilities on the accompanying balance sheet. See Note 12—Subsequent Events for details regarding an extension to the exercise period of the Short-Term Warrants and the tender offer to induce holders of the Short-Term Warrants and March Long-Term Warrants to exercise at a significantly reduced exercise price per share.

Additional Issuance of Warrants

On April 25, 2019, the Company entered into an amendment (the "Amendment") to the Purchase Agreement dated as of March 17, 2019, between the Company and each purchaser party thereto. The Amendment (i) deleted Section 4.12 of the Purchase Agreement, which generally prohibited the Company from issuing, entering into agreements to issue, announcing proposed issuances, selling or granting certain securities between the date of the Purchase Agreement and the date that was 45 days following the closing date thereunder and (ii) gave each purchaser the right to purchase, for $0.125 per underlying share, an additional warrant to purchase shares of the Company's common stock having an exercise price per share of $2.13 and otherwise having the terms of the March Long-Term Warrants (collectively, the "New Warrants") pursuant to a securities purchase agreement to be entered into among the Company and each purchaser that desires to purchase the New Warrants. On May 17, 2019, the Company and each purchaser entered into such Securities Purchase Agreement (the "New Agreement"), and the Company issued New Warrants exercisable for an aggregate of 3,897,010 shares of the Company's common stock.

The New Warrants are exercisable for five years beginning on the six-month anniversary of the date of issuance until the five-year anniversary of their date of issuance. The New Warrants have an initial exercise price equal to $2.13 per share, subject to certain adjustments. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to the Company, provided that any increase in such percentage shall not be effective until 61 days after such notice. If not previously exercised in full, at the expiration of their applicable terms, the New Warrants will be automatically

exercised via cashless exercise, in which case the holder would receive upon such exercise the net number of shares, if any, of common stock determined according to the formula set forth in the New Warrants. The New Warrants are classified as warrant liabilities on the accompanying balance sheet. See Note 12—Subsequent Events for details regarding a tender offer to induce holders of the New Warrants to exercise at a significantly reduced exercise price per share.

April 2019 Offering

On April 29, 2019, the Company entered into a Securities Purchase Agreement (the "April Purchase Agreement") with certain institutional and accredited investors providing for the sale by the Company of up to 4,318,272 shares of its common stock at a purchase price of $2.025 per share.

Pursuant to the April Purchase Agreement, the Company agreed to issue unregistered warrants (the "April Warrants") to purchase up to 4,318,272 shares of common stock. Subject to certain ownership limitations, the April Warrants were exercisable beginning on the date of their issuance until the five-and-a-half-year anniversary of their date of issuance at an initial exercise price of $2.13 per share. The exercise price of the April Warrants was subject to adjustment for stock splits, reverse splits, and similar capital transactions as described in the April Warrants. If not previously exercised in full, at the expiration of their terms, the April Warrants would have been automatically exercised via cashless exercise.

The net proceeds from the offering and the private placement were approximately $7.9 million, after deducting commissions and estimated offering costs. The Company granted the placement agent warrants to purchase up to 215,914 shares of common stock (the "Placement Agent Warrants"). The Placement Agent Warrants had substantially the same terms as the April Warrants, except that the Placement Agent Warrants had an exercise price of $2.53 per share and had a term of 5 years from the effective date of the offering. The Company also paid the placement agent a reimbursement for non-accountable expenses in the amount of $35,000 and a reimbursement for legal fees and expenses of the placement agent in the amount of $25,000. On December 19, 2019, the Company and each of the purchasers of the April Warrants and Placement Agent Warrants (collectively, the "Exchange Warrants") entered into separate exchange agreements (the "Exchange Agreements"), pursuant to which the Company agreed to issue to the purchasers an aggregate of 5,441,023 shares of the Company's common stock (the "Exchange Shares"), at a ratio of 1.2 Exchange Shares for each purchaser warrant in exchange for the cancellation and termination of all of the outstanding Exchange Warrants.

Merger with RDD Pharma, Ltd.

On October 6, 2019, the Company entered into an Agreement and Plan of Merger and Reorganization (the "RDD Merger Agreement") pursuant to which the Company agreed to acquire all of the outstanding capital stock of privately held RDD Pharma, Ltd. ("RDD"), an Israel Corporation, in exchange for a combination of common and preferred shares to be issued by the Company to the existing RDD shareholders (the "RDD Merger"). The RDD Merger includes a concurrent capital raise led by OrbiMed Advisors, LLC, with a minimum funding requirement of $10,000,000 (the "RDD Merger Financing").

At the effective time of the RDD Merger, all outstanding ordinary and preferred shares of RDD, nominal value of NIS 0.01 each, will be converted into the right to receive such number of validly issued, fully paid and non-assessable Company common stock. Additionally, each outstanding RDD stock option will be converted into and become an option exercisable for the Company's common stock. Each outstanding RDD warrant will be exercised or cancelled prior to the effective time. Following completion of the RDD Merger, on an as-converted, fully-diluted basis, the current Innovate stockholders will own approximately 62.0% of the combined company's capital stock and the current RDD stockholders will own approximately 38.0% of the combined company's capital stock. The final ownership percentages are subject to dilution based on the final amount of capital invested in the RDD Merger Financing, which will dilute both the current Innovate stockholders and RDD stockholders on a pro rata basis.

Promptly following the effective time of the RDD Merger, the Company intends to file an amendment to its certificate of incorporation to change its name from Innovate Biopharmaceuticals, Inc. to 9 Meters Biopharma, Inc. The closing of the RDD Merger is subject to certain other conditions, unless such conditions are waived, including, among others, (i) the absence of certain laws, orders, judgments and injunctions that restrain, enjoin or otherwise prohibit the consummation of the RDD Merger, (ii) subject to certain exceptions, the accuracy of representations and warranties with respect to the businesses of the Company and RDD and compliance in all material respects by the Company and RDD with their respective covenants contained in the RDD Merger Agreement, (iii) the absence of a material adverse effect on the Company's or RDD's businesses, (iv) the approval by Nasdaq to list the company shares to be issued in the RDD Merger, (v) the expiration of statutory waiting periods required under Israeli law and (vi) the receipt of certain tax rulings from the Israeli Tax Authorities.

Business Risks

The Company faces risks associated with biopharmaceutical companies whose products are in various stages of development. These risks include, among others, the Company's need for additional financing to achieve key development milestones, the need to defend intellectual property rights and the dependence on key members of management.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and disclosures made in the accompanying notes to the financial statements. Areas of the financial statements where estimates may have the most significant effect include accrued expenses, share-based compensation, valuation of the derivative liability and warrant liabilities, valuation allowance for income tax assets and management's assessment of the Company's ability to continue as a going concern. Changes in the facts or circumstances underlying these estimates could result in material changes and actual results could differ from these estimates.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. While cash held by financial institutions may at times exceed federally insured limits, management believes that no material credit or market risk exposure exists due to the high quality of the financial institutions. The Company has not experienced any losses on such accounts.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash and cash equivalents. Cash equivalents are stated at cost and consist primarily of money market accounts.

Restricted Deposit

The Company maintains a certificate of deposit ("CD") with a bank, which matures on October 17, 2020 and pays interest at a rate of 1.56% per annum. The CD serves as collateral for the Company's credit cards.

Property and Equipment

The Company records property and equipment at cost. Improvements and betterments that add new functionality or extend the useful life of the asset are capitalized, while general repairs and maintenance are expensed as incurred. The Company depreciates its property and equipment over the estimated useful lives of the assets, typically three years, using the straight-line method. Leasehold improvements are amortized over the lesser of their estimated useful lives or the lives of the underlying leases, whichever is shorter. Depreciation and amortization expense for property and equipment and leasehold improvements has been included in general and administrative expenses in the accompanying statements of operations and comprehensive loss.

Accrued Expenses

The Company incurs periodic expenses such as research and development, licensing fees, salaries and benefits and professional fees. The Company is required to estimate its expenses resulting from obligations under contracts with clinical research organizations, vendors and consulting agreements that have been incurred by the Company prior to being invoiced. This process involves reviewing quotations and contracts, identifying services that have been performed on the Company's behalf and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual cost. The majority of the Company's service providers invoice monthly in arrears for services performed or when contractual milestones are met. The Company estimates accrued expenses as of each balance sheet date based on facts and circumstances known at that time.

Accrued expenses consisted of the following:

	December 31,	
	2019	2018
Accrued compensation and benefits	$ 574,332	$ 697,334
Accrued clinical expenses	4,143,269	58,151
Other accrued expenses	30,150	70,842
Total	$ 4,747,751	$ 826,327

Derivative Liability

The Company accounts for derivative instruments in accordance with Accounting Standards Codification ("ASC") 815, *Derivative and Hedging*, which establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other financial instruments or contracts and requires recognition of all derivatives on the balance sheet at fair value. The Company's derivative financial instrument consists of an embedded option in the Company's convertible debt. The embedded derivative includes provisions that provide the noteholder with certain conversion and put rights at various conversion or redemption values as well as certain call options for the Company. See Note 6—Debt for further details.

Warrant Liabilities

The warrants the Company issued during 2019 are freestanding financial instruments that contain net settlement options and may require the Company to settle these warrants in cash under certain circumstances. As such, the Company has classified these warrants as liabilities on the accompanying balance sheets. The warrant liabilities are initially recorded at fair value on the date of issuance and will be subsequently re-measured to fair value at each balance sheet date until the warrant liabilities are settled. Changes in the fair value of the warrants are recognized as a non-cash component of other income and expense in the accompanying statements of operations and comprehensive loss.

Research and Development

Research and development expenses consist of costs incurred to further the Company's research and development activities and include salaries and related employee benefits, manufacturing of pharmaceutical active ingredients and drug products, costs associated with clinical trials, nonclinical activities, regulatory activities, research-related overhead expenses and fees paid to expert consultants, external service providers and contract research organizations which conduct certain research and development activities on behalf of the Company. Costs incurred in the research and development of products are charged to research and development expense as incurred.

Costs for preclinical studies and clinical trial activities are recognized based on an evaluation of the vendors' progress towards completion of specific tasks, using data such as patient enrollment, clinical site activations or information provided by vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services were performed. The Company determines accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. The estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. Although the Company does not expect its estimates to be materially different from amounts incurred, the Company's estimates and assumptions for clinical trial costs could differ significantly from actual costs incurred, which could result in increases or decreases in research and development expenses in future periods when actual results are known.

Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the goods have been received or when the activity is performed, rather than when payment is made.

Share-Based Compensation

The Company recognizes share-based compensation expense for grants of stock options to employees and non-employee members of the Board based on the grant-date fair value of those awards using the Black-Scholes option-pricing model. Share-based compensation expense is generally recognized on a straight-line basis over the requisite service period for awards expected to vest.

Prior to adoption of Accounting Standards Update ("ASU") 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Non-employee Share-Based Payment Accounting*, share-based compensation expense related to stock options granted to non-employees, other than non-employee directors, was adjusted each reporting period for changes in the fair value of the Company's stock until the measurement date. The measurement date was generally considered to be the date when all services had been rendered or the date that options were fully vested. Effective January 1, 2019, the Company adopted ASU 2018-07, which no longer requires the re-measurement of the fair value for stock options awarded to non-employees. ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees.

Share-based compensation expense for both employees and non-employees includes an estimate, which is made at the time of grant, of the number of awards that are expected to be forfeited. This estimate is revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Under the Black-Scholes option-pricing model, fair value is calculated based on assumptions with respect to:

- *Expected dividend yield.* The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on the Company's common stock.
- *Expected stock price volatility.* Due to limited trading history as a public company, the expected volatility is derived from the average historical volatilities of publicly traded companies within the Company's industry that the Company considers to be comparable to the Company's business over a period approximately equal to the expected term. In evaluating comparable companies, the Company considers factors such as industry, stage of life cycle, financial leverage, size and risk profile.
- *Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities approximately equal to the expected term.
- *Expected term.* The expected term represents the period that the stock-based awards are expected to be outstanding. Due to limited history of stock option exercises, the Company estimates the expected term of employee stock options based on the simplified method, which calculates the expected term as the average of the time-to-vesting and the contractual life of the options. Pursuant to ASU 2018-07, the Company has elected to use the contractual life of the option as the expected term for non-employee options.

Periodically, the Board may approve the grant of restricted stock units ("RSUs") pursuant to the Innovate Biopharmaceuticals, Inc. 2012 Omnibus Incentive Plan, as amended, which represent the right to receive shares of the Company's common stock based on terms of the agreement. The fair value of RSUs is recognized as share-based compensation expense generally on a straight-line basis over the service period, net of estimated forfeitures. The grant date fair value of an RSU represents the closing price of the Company's common stock on the date of grant.

Income Taxes

The Company accounts for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statements and the tax basis of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to reverse.

Net deferred tax assets are recognized to the extent the Company's management believes these assets will more likely than not be realized. In making such determination, management considers all positive and negative evidence, including reversals of existing temporary differences, projected future taxable income, tax planning strategies and recent financial operations. A valuation allowance is recorded to reduce the deferred tax assets reported if, based on the weight of the evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Management periodically reviews its deferred tax assets for recoverability and its estimates and judgments in assessing the need for a valuation allowance.

The Company recognizes a tax benefit from uncertain positions when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. Income tax positions must meet a more-likely-than-not recognition threshold to be recognized.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received for sale of an asset or paid for transfer of a liability, in an orderly transaction between market participants at the measurement date. U.S. GAAP establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). Financial instruments recorded in the accompanying balance sheets are categorized based on the inputs to valuation techniques as follows:

- Level 1 — defined as observable inputs based on unadjusted quoted prices for identical instruments in active markets;
- Level 2 — defined as inputs other than Level 1 that are either directly or indirectly observable in the marketplace for identical or similar instruments in markets that are not active; and
- Level 3 — defined as unobservable inputs in which little or no market data exists where valuations are derived from techniques in which one or more significant inputs are unobservable.

The fair value of the embedded derivative issued in connection with the Senior Convertible Note and the Unsecured Convertible Note, further described in Note 6—Debt, was determined by using a Monte Carlo simulation technique ("MCS") to value the embedded derivative associated with each note. As part of the MCS valuation a discounted cash flow ("DCF") model is used to value the debt on a stand-alone basis and determine the discount rate to utilize in both the DCF and MCS models. The significant estimates used in the DCF model include the time to maturity of the convertible debt and calculated discount rate, which includes an estimate of the Company's specific risk premium. The MCS methodology calculates the theoretical value of an option based on certain parameters, including (i) the threshold of exercising the option, (ii) the price of the underlying security, (iii) the time to expiration, or expected term, (iv) the expected volatility of the underlying security, (v) the risk-free rate and (vi) the number of paths.

These valuation techniques involve management's estimates and judgment based on unobservable inputs and are classified in Level 3. The table below summarizes the valuation inputs into the MCS model for the derivative liability associated with the Senior Convertible Note as of December 31, 2018 and for the derivative liability associated with the Unsecured Convertible Note as of March 8, 2019 and December 31, 2019.

	Derivative Liability		
	December 31, 2019	**March 8, 2019**	**December 31, 2018**
Expected dividend yield	—	—	—
Discount rate	29.1%	29.3%	13.6%
Expected stock price volatility	96.0%	101.1%	105.6%
Risk-free interest rate	1.6%	2.5%	2.5%
Expected term	14 months	24 months	21 months
Price of the underlying common stock	$ 0.56	$ 1.99	$ 2.31

The fair values of the warrants at their respective dates of issuance further described above in the sections entitled "March 2019 Offering," "Additional Issuance of Warrants," and "April 2019 Offering" were determined through the use of an MCS model. The MCS methodology calculates the theoretical value of an option based on certain parameters, including (i) the threshold of exercising the option, (ii) the price of the underlying security, (iii) the time to expiration, or expected term, (iv) the expected volatility of the underlying security, (v) the risk-free interest rate and (vi) the number of paths. Given the high level of the selected volatilities, the methodology selected simulates the Company's market value of invested capital ("MVIC") through the maturity date of the respective warrants (ranging from one year to five-and-a-half years). Further, the estimated future stock price of the Company is calculated by subtracting the debt plus accrued interest from the MVIC. The significant estimates used in the MCS model include management's estimated probability of future financing and liquidation events.

Upon a fundamental transaction (as defined in the applicable warrant agreement), each holder of Short-Term Warrants and each holder of the March Long-Term Warrants and New Warrants (collectively, the "Long-Term Warrants") can elect to require

the Company or a successor entity to purchase such holder's outstanding, unexercised warrants for a cash payment (or under certain circumstances other consideration) equal to the Black-Scholes value of the warrants on the date of consummation of the fundamental transaction, calculated in accordance with the terms and using the assumptions specified in the applicable warrant agreement. Due to the proposed RDD Merger, the Company entered into the Exchange Agreements with the holders of the Exchange Warrants, pursuant to which the Company agreed to issue the purchasers an aggregate of 5,441,023 shares in exchange for the cancellation and termination of the Exchange Warrants. On December 26, 2019, an aggregate of 2,994,762 warrants were exchanged for 3,593,714 shares of the Company's common stock. Immediately prior to the exchange, the Company determined the fair value of the Exchange Warrants as of December 25, 2019 and recognized a gain in fair value of the Exchange Warrants of approximately $0.2 million in the accompanying statement of operations and comprehensive loss. The remaining outstanding Exchange Warrants were exchanged subsequent to December 31, 2019. See Note 12—Subsequent Events for further details. During the year ended December 31, 2019, the Company recognized warrant inducement expense of approximately $1.3 million. There was no warrant inducement expense during the year ended December 31, 2018. The warrant inducement expense represents the accounting fair value of consideration issued to induce conversion of the Exchange Warrants at a ratio of 1.2 Exchange Shares for each purchaser warrant.

Management has assumed that the holders of the Short-Term Warrants and Long-Term Warrants would elect to receive cash payments under the respective warrant agreements following completion of the RDD Merger. As such, the Company determined the fair value of the Short-Term Warrants and Long-Term Warrants as of December 31, 2019, for financial reporting purposes, through the use of the Black-Scholes model, which resulted in a significant change in the fair value estimate compared to the fair value estimate at the date of issuance. The estimates underlying the assumptions used in both the MCS model and Black-Scholes model are subject to risks and uncertainties and may change over time, and the assumptions used in both the MCS model and the Black-Scholes model for financial reporting purposes generally differ from the assumptions that would be applied in determining a payout under the applicable warrant agreements. These valuation techniques involve management's estimates and judgment based on unobservable inputs and are classified in Level 3.

The table below summarizes the valuation inputs into the MCS model for the Short-Term Warrants and Long-Term Warrants at their respective dates of issuance.

	Short-Term Warrants	Long-Term Warrants	
	March 18, 2019	March 18, 2019	May 17, 2019
Conversion price	$ 4.00	$ 2.56	$ 2.13
Expected stock price volatility	122.0%	85.2%	83.4%
Risk-free interest rate	2.5%	2.2%	2.2%
Expected term	1 year	5 years	5 years
Price of the underlying common stock	$ 2.48	$ 2.48	$ 1.58

The table below summarizes the range of valuation inputs into the Black-Scholes model for the Exchange Warrants on their date of issuance and immediately prior to the exchange.

	Exchange Warrants	
	May 1, 2019	December 25, 2019
Conversion price	$ 2.13 - $ 2.53	$ 2.13 - $ 2.53
Expected stock price volatility	84.1%	87.3% - 88.9%
Risk-free interest rate	2.2%	1.7%
Expected term	5 - 5.5 years	4.4 - 4.9 years
Price of the underlying common stock	$ 1.54	$ 0.56

The table below summarizes the range of valuation inputs into the Black-Scholes model for the outstanding Short-Term Warrants and Long-Term Warrants as of December 31, 2019 and excludes the Exchange Warrants disclosed above.

	Short-Term Warrants	Long-Term Warrants
	December 31, 2019	
Conversion price	$ 4.00	$2.13 - $2.56
Expected stock price volatility	97.6%	87.3% - 89.3%
Risk-free interest rate	1.5%	1.7%
Expected term	3 months	4.2 - 4.3 years
Price of the underlying common stock	$ 0.56	$ 0.56

The following table summarizes the fair value hierarchy of financial liabilities measured at fair value as of December 31, 2019 and 2018, respectively.

	December 31, 2019			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Derivative liability	$ —	$ —	$ 408,000	$ 408,000
Warrant liabilities	—	—	2,637,500	2,637,500
Total liabilities at fair value	$ —	$ —	$ 3,045,500	$ 3,045,500

	December 31, 2018			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Derivative liability	$ —	$ —	$ 370,000	$ 370,000
Warrant liabilities	—	—	—	—
Total liabilities at fair value	$ —	$ —	$ 370,000	$ 370,000

The following table summarizes the changes in fair value of the derivative liability and warrant liabilities classified in Level 3. Gains and losses reported in this table include changes in fair value that are attributable to unobservable inputs.

	Year Ended	
	December 31, 2019	December 31, 2018
Beginning balance	$ 370,000	$ —
Issuance of warrant liabilities	3,330,000	—
Addition of derivative liability	—	420,000
Extinguishment of derivative liability (the Senior Convertible Note)	(370,000)	—
Issuance of derivative liability (the Unsecured Convertible Note)	1,281,000	—
Exchange of the April Warrants and Placement Agent Warrants	(746,700)	
Change in fair value of warrant liabilities	54,200	—
Change in fair value of derivative liability	(873,000)	(50,000)
Ending balance	$ 3,045,500	$ 370,000
The amount of total gains (losses) for the period included in earnings attributable to the change in unrealized gains (losses) relating to the fair value liabilities still held at the end of the period	$ 1,347,900	$ 50,000

The cumulative unrealized loss relating to the change in fair value of the derivative liability and warrant liabilities of $1,347,900 and the gain on extinguishment of derivative liability of $370,000 for the year ended December 31, 2019 is included in other income (expense) in the statements of operations and comprehensive loss. The gain of $50,000 for the year ended December 31, 2018 from the change in fair value of derivative liability is included in other income (expense) on the accompanying statements of operations and comprehensive loss.

ASC 820, *Fair Value Measurement and Disclosures* requires all entities to disclose the fair value of financial instruments, both assets and liabilities, for which it is practicable to estimate fair value. As of December 31, 2019 and 2018, the recorded values of cash and cash equivalents, restricted deposit, accounts payable, accrued expenses and convertible promissory notes approximate their fair values due to the short-term nature of the instruments.

Deferred Offering Costs

Deferred offering costs consist principally of legal, accounting and underwriters' fees related to offerings or the Company's shelf registration. Offering costs incurred prior to an offering are initially capitalized and then subsequently reclassified to additional paid-in capital upon completion of the offering. Deferred offering costs associated with the shelf registration will be charged to additional paid-in capital on a pro-rata basis in the event the Company completes an offering under the shelf registration. Due to the voluntary suspension of the "at-the-market" ("ATM") facility effective June 24, 2019, deferred offering costs associated with the ATM facility were written off during the year ended December 31, 2019.

Patent Costs

Costs associated with the submission of patent applications are expensed as incurred given the uncertainty of the future economic benefits of the patents. Patent and patent related legal and administrative costs included in general and administrative expenses were approximately $475,000 and $513,000 for the years ended December 31, 2019 and 2018, respectively.

Net Loss Per Share

The Company calculates net loss per share as a measurement of the Company's performance while giving effect to all potentially dilutive shares that were outstanding during the reporting period. Because the Company had a net loss for all periods presented, the inclusion of common stock options or other similar instruments would be anti-dilutive. Therefore, the weighted- average shares outstanding used to calculate both basic and diluted net loss per share are the same. For the years ended December 31, 2019 and 2018, 22.8 million and 9.0 million potentially dilutive securities related to warrants and stock options issued and outstanding have been excluded from the computation of diluted weighted-average shares outstanding because the effect would be anti-dilutive. The potentially dilutive securities consisted of the following:

	Year Ended December 31,	
	2019	2018
Options outstanding under the Private Innovate Plan	6,063,745	6,340,871
Options outstanding under the Omnibus Plan	2,717,870	776,131
Warrants issued at a weighted-average exercise price of $55.31	154,403	154,403
Warrants issued at an exercise price of $2.54	349,555	349,555
Warrants issued at an exercise price of $3.18	1,410,358	1,410,358
Short-term warrants issued at an exercise price of $4.00	4,181,068	—
Long-term warrants issued at a weighted-average exercise price of $2.27	7,945,068	—
Total	22,822,067	9,031,318

Comprehensive Loss

Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. The Company is required to record all components of comprehensive loss in the financial statements in the period in which they are recognized. Net loss and other comprehensive loss, including unrealized gains and losses on investments are reported, net of their related tax effect, to arrive at a comprehensive loss. For the years ended December 31, 2019 and 2018, comprehensive loss was equal to net loss.

Segments

Operating segments are defined as components of an enterprise engaging in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company operates and manages its business as one operating segment and all of the Company's operations are in North America.

Recently Issued Accounting Standards

Accounting Pronouncements Adopted

The Company adopted ASU No. 2016-02, *Leases (Topic 842)*, as amended, as of January 1, 2019 using the modified retrospective approach at the beginning of the period of adoption. Under this approach, the reporting for comparative periods presented in the financial statements are presented in accordance with the legacy lease standard. In addition, the Company elected the available practical expedients permitted under the transition guidance within the new lease standard.

Under the new leases standard, the Company recognizes a right-of-use ("ROU") asset and lease liability upon commencement of a lease. The ROU asset represents the Company's right to use an underlying asset for the lease term and is included in right-of-use asset on the accompanying balance sheet. Lease liabilities represent the Company's obligation to make lease payments arising from the lease and are included in current lease liability on the accompanying balance sheet. Operating lease ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. In the absence of an implicit rate, the Company uses their incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. All leases with a term of less than 12 months are not recognized on the balance sheet. Adoption of the new leases standard resulted in the Company recognizing a ROU asset and lease liability of less than $0.1 million as of January 1, 2019. The adoption of ASU 2016-02 did not result in a cumulative adjustment to accumulated deficit.

In June 2018, the Financial Accounting Standards Board ("FASB") issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Non-employee Share-Based Payment Accounting.* ASU 2018-07 expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. The Company adopted this standard effective January 1, 2019. Effective January 1, 2019, the date of adoption, the Company changed its expense recognition for share-based payments to non-employees to an amount determined at the grant or modification date instead of a variable amount to be re-measured each reporting period. The Company calculated the fair value of its non-employee grants as of the adoption date and determined that there was no impact to the Company's accumulated deficit or other components of equity upon adoption of ASU 2018-07. The unamortized expense for non-employee grants will be recognized on a straight-line

basis over the remaining contractual term of the respective non-employee option agreements. The adoption of ASU 2018-07 did not have a material impact on the Company's financial statements.

Accounting Pronouncements Being Evaluated

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement.* This standard no longer requires public companies to disclose transfers between Level 1 and 2 of the fair value hierarchy and adds additional disclosure requirements about the range and weighted average used to develop significant unobservable inputs for Level 3 fair value measurements. The guidance is effective for fiscal years beginning after December 15, 2019, and for interim periods within those fiscal years. Early adoption is permitted and the Company is currently evaluating the impact this standard will have on the Company's financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.* ASU 2019-12 amends the accounting for income taxes by removing certain exception to the general principles in Topic 740 and improves consistent application of other areas of Topic 740 by clarifying and amending existing guidance. ASU 2019-12 is effective for fiscal years and interim periods within those fiscal years beginning after December 15, 2020. Early adoption is permitted and the Company is currently evaluating the impact this standard will have on the Company's financial statements.

NOTE 2: LIQUIDITY AND GOING CONCERN

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has concluded that the prevailing conditions and ongoing liquidity risks faced by the Company raise substantial doubt about the Company's ability to continue as a going concern for at least one year following the date these financial statements are issued. Management's near-term plans include a business combination with RDD and a concurrent financing further described in Note 1—Summary of Significant Accounting Policies. In addition, the Company may consider entering into strategic partnerships or licensing arrangements or seeking additional debt or equity financing arrangements or a combination of these activities. Should the RDD Merger and the RDD Merger Financing not be completed when currently expected, the Company will need to seek immediate sources of capital. Based on the Company's limited operating history, recurring negative cash flows from operations, current plans and available resources, the Company will need substantial additional funding to support its planned and future operating activities, including progression of research and development programs. There can be no assurance that the Company will be able to obtain additional capital on terms acceptable to the Company, on a timely basis or at all. The failure to obtain sufficient additional funding or enter into strategic partnerships could adversely affect the Company's ability to achieve its business objectives and product development timelines and could have a material adverse effect on the Company's results of operations. The accompanying financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

NOTE 3: MONSTER MERGER AND FINANCING

As noted above, on January 29, 2018, Private Innovate and Monster completed the Monster Merger in accordance with the terms of the Monster Merger Agreement. Pursuant to the Monster Merger Agreement, Monster Merger Sub merged with and into IB Pharmaceuticals, with IB Pharmaceuticals surviving as the wholly owned subsidiary of Monster. Immediately following the Monster Merger, Monster changed its name to Innovate Biopharmaceuticals, Inc. On March 29, 2018, IB Pharmaceuticals was merged into Innovate and ceased to exist.

Immediately prior to the closing of the Monster 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 $1.6 million in placement agent fees and expenses (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 an exercise price of $3.18 per share after giving effect to the Exchange Ratio. The Company calculated the fair value of the warrants issued utilizing the Black-Scholes option pricing model with the following assumptions: expected dividend yield of 0.0%, expected stock price volatility of 84.8%, risk free rate of 2.5% and term of 5.0 years. The proceeds were allocated between common stock and warrants utilizing the relative fair value method with the allocated warrant value of approximately $2.0 million recorded as additional paid-in capital.

Private Innovate also issued 349,555 five-year warrants with an exercise price of $2.54 per share and 279,862 five-year warrants with an exercise price of $3.18 per share (after giving effect to the Exchange Ratio) to the respective placement agents and their affiliates. The Company calculated the fair value of the warrants issued utilizing the Black-Scholes option pricing model with the following assumptions: expected dividend yield of 0.0%, expected stock price volatility of 84.8%, risk free rate of 2.5% and term of 5.0 years. The total value for these warrants approximated $913,000 and was recorded as stock issuance costs and additional paid-in capital.

Concurrently with the Equity Issuance, convertible promissory notes issued by Private Innovate in the aggregate principal amount of approximately $8.6 million plus accrued interest of $582,000 were converted into shares of Private Innovate common stock at a price per share of $0.72, prior to the Exchange Ratio (the "Conversion"), which reflected a 25% discount relative to the shares issued pursuant to the Equity Issuance (the "Conversion Discount"). The Conversion Discount represented a beneficial conversion feature of approximately $3.1 million which was recorded as a charge to interest expense and a credit to additional paid-in capital.

NOTE 4: PROPERTY AND EQUIPMENT

Property and equipment consisted of the following as of December 31, 2019 and 2018:

	December 31,	
	2019	2018
Furniture and fixtures	$ 11,552	$ 11,552
Computer equipment	34,179	22,245
Leasehold improvements	27,446	27,446
Property and equipment, gross	$ 73,177	$ 61,243
Less: Accumulated depreciation	(47,755)	(26,148)
Property and equipment, net	$ 25,422	$ 35,095

Depreciation expense for property and equipment was approximately $22,000 and $20,000 for the years ended December 31, 2019 and 2018, respectively.

NOTE 5: RELATED PARTY TRANSACTIONS

Consulting Agreements

During the years ended December 31, 2019 and 2018, the Company received consulting services from one of its executive officers prior to his appointment as an executive officer of the Company in 2019. During the years ended December 31, 2019 and 2018, the Company incurred consulting expenses with this executive officer of approximately $115,000 and $31,000, respectively. As of December 31, 2018, approximately $31,000, was owed to this consultant and included in accounts payable on the accompanying balance sheet. There were no amounts due under the consulting agreement as of December 31, 2019.

Equity Financing

Pursuant to the Purchase Agreement with SDS Capital Partners II, LLC and certain other accredited investors, in March 2019, the Company issued an aggregate of 4,181,068 shares of common stock at a price of $2.33 per share. Concurrently, the Company issued the Short-Term Warrants and the March Long-Term Warrants, of which 4,181,068 are exercisable immediately. See Note 1—Summary of Significant Accounting Policies for further details regarding the March 2019 Offering and Additional Issuance of Warrants.

Of the shares and warrants issued in March 2019, 50,000 shares of common stock were issued to GSB Holdings, Inc., a family-owned company of David Clarke, who previously served as Chief Executive Officer and Chairman of the Board of the Company prior to the Monster Merger. The aggregate purchase price of the common stock shares issued to GSB Holdings, Inc. was $116,500. In addition, the Company issued GSB Holdings, Inc. Short-Term Warrants to purchase 50,000 shares of common

stock, which were exercisable immediately, had an expiration date of March 18, 2020 and had an initial exercise price of $4.00 per share. The Company also issued GSB Holdings, Inc. March Long-Term Warrants to purchase 30,000 shares of common stock which became exercisable on the six-month anniversary of March 18, 2019, had an expiration date of March 18, 2024 and had an initial exercise price of $2.56 per share.

In April 2019, the Company entered into the Amendment, between the Company and each purchaser, including GSB Holdings, Inc. The Amendment gave each purchaser the right to purchase, for $0.125 per underlying share, an additional warrant to purchase shares of the Company's common stock having an initial exercise price per share of $2.13 and otherwise having the terms of the March Long-Term Warrants.

The Company issued New Warrants exercisable for an aggregate of 3,897,010 shares of the Company's common stock and the New Warrants are exercisable for five years beginning on the six-month anniversary of the date of issuance. The New Warrants have an initial exercise price equal to $2.13 per share, subject to certain adjustments. Pursuant to the New Securities Purchase Agreement, GSB Holdings, Inc. received New Warrants to purchase an additional 46,638 shares of the Company's common stock. See Note 12—Subsequent Events for further details regarding the extension of the Short-Term Warrants and an offer to amend and exercise the Short-Term Warrants, March Long-Term Warrants and New Warrants.

NOTE 6: DEBT

Senior Convertible Note

On January 29, 2018, the Company entered into a Note Purchase Agreement and Senior Note Payable (the "Note") with a lender. The principal amount of the Note was $4.8 million ("Original Principal"). The Note was issued at a discount of $1.8 million and net of $20,000 for financing costs, for total proceeds of $3.0 million. The discount and additional repayment premium were amortized to interest expense using the effective interest method through the scheduled maturity date of September 30, 2018 (the "Maturity Date"). Interest on the Note accrued from January 29, 2018, at a rate of 12.5% per annum and quarterly payments of interest only were due beginning on March 30, 2018 and compounded quarterly. The Company entered into a Waiver Agreement with the noteholder that extended the Maturity Date until October 4, 2018. On October 4, 2018, the Company entered into an Amendment and Exchange Agreement ("Note Exchange Agreement") with the noteholder exchanging the Note for a new Senior Convertible Note (the "Senior Convertible Note").

The principal amount of the Senior Convertible Note was $5.2 million and bore interest at a rate of eight percent (8%) per annum payable quarterly in cash, with a scheduled maturity date of October 4, 2020. The interest rate would automatically increase to 18% per annum if there was an event of default during the period. The Company evaluated the Note Exchange Agreement and the Senior Convertible Note and determined that the amendment to the Note constituted an extinguishment of debt, in accordance with authoritative guidance. The Company determined that there was no difference between the reacquisition price of the new debt and the net carrying amount of the extinguished debt and thus there was no gain or loss from the extinguishment. The Company incurred approximately $30,000 of legal fees associated with the Senior Convertible Note, which were recorded as debt issuance costs and are included in the amortization of debt discount discussed below.

The various conversion and redemption features contained in the Senior Convertible Note are embedded derivative instruments, which were recorded as a debt discount and derivative liability at their estimated fair value. See Note 1-Summary of Significant Accounting Policies for details regarding the fair value of derivative liability. During 2018, the volume weighted- average price ("VWAP") of the Company's common stock was lower than the Floor Price for more than ten consecutive days. As such, the noteholder had the right to require the Company to redeem the Senior Convertible Note prior to December 31, 2018, at its option. Therefore, the Company has amortized the entire debt discount to interest expense through the triggering of the redemption option, which occurred in 2018. Based on the conversion features, redemption features and subjective acceleration clauses contained in the Senior Convertible Note, the Company recorded the Senior Convertible Note as a short-term obligation as of December 31, 2018.

During January 2019, the noteholder issued a redemption notice to the Company requiring the Company to repay the noteholder $1,049,167 of principal and $1,399 of accrued interest. On January 7, 2019, the Company entered into an Option to

Purchase Senior Convertible Note (the "Option Agreement") with the noteholder. The Company paid the noteholder $250,000 in consideration for the noteholder entering into the Option Agreement with the Company, which was recorded as interest expense in the accompanying statements of operations and comprehensive loss. The Option Agreement provided the Company with the ability to repay (purchase) the outstanding principal and accrued interest of the Senior Convertible Note any time from January 7, 2019 until March 31, 2019 ("Option Period").

During March 2019, the Company exercised its repurchase rights under the Option Agreement and paid the noteholder of the Senior Convertible Note approximately $5.2 million in principal and $60,000 in interest, which was the full purchase amount of the Senior Convertible Note pursuant to the terms of the Option Agreement. There are no further amounts outstanding under the Senior Convertible Note and the Senior Convertible Note has been canceled. The Company accounted for the repayment of the Senior Convertible Note as a liability extinguishment in accordance with ASC 405, *Extinguishments of Liabilities*, which resulted in the Company recording a loss on extinguishment of debt of approximately $1.0 million in the accompanying statements of operations and comprehensive loss for the year ended December 31, 2019.

Amortization of the debt discount for the Note and Senior Convertible Note recorded as interest expense was approximately $2.5 million for the year ended December 31, 2018. There was no such expense for the Note and Senior Convertible Note during the year ended December 31, 2019.

Unsecured Convertible Promissory Note

On March 8, 2019, the Company entered into a Securities Purchase Agreement (the "Note Purchase Agreement") with a purchaser (the "Convertible Noteholder"). Pursuant to the Note Purchase Agreement, the Company issued the Convertible Noteholder an unsecured Convertible Promissory Note (the "Unsecured Convertible Note") in the principal amount of $5.5 million. The Convertible Noteholder may elect to convert all or a portion of the Unsecured Convertible Note at any time and from time to time into the Company's common stock at a conversion price of $3.25 per share, subject to adjustment for stock splits, dividends, combinations and similar events. The Company may prepay all or a portion of the Unsecured Convertible Note at any time for an amount equal to 115% of then outstanding obligations or the portion of the obligations the Company is prepaying. The purchase price of the Unsecured Convertible Note was $5.0 million, and the Unsecured Convertible Note carries an original issuance discount ("OID") of $0.5 million, which is included in the principal amount of the Unsecured Convertible Note. In addition, the Company agreed to pay $20,000 of transaction expenses, which were netted out of the purchase price of the Unsecured Convertible Note. The Company also incurred additional transaction costs of approximately $37,000, which were recorded as debt issuance costs. As a result of the redemption features of the Unsecured Convertible Note, further described below, the Company is amortizing the debt issuance costs and accreting the OID to interest expense over the estimated redemption period of 15 months, using the effective interest method.

The various conversion and redemption features contained in the Unsecured Convertible Note are embedded derivative instruments, which were recorded as a debt discount and derivative liability at the issuance date at their estimated fair value of $1.3 million. Amortization of debt discount and accretion of the OID for the Unsecured Convertible Note recorded as interest expense was approximately $1.1 million for the year ended December 31, 2019.

The convertible notes payable as of December 31, 2019 and 2018 consist of the following:

	December 31,	
	2019	**2018**
Convertible notes payable, net	$ 5,500,000	$ 5,196,667
Less: principal payments of debt	(1,544,724)	—
Less: unamortized debt discount and OID	(770,621)	—
Total	$ 3,184,655	$ 5,196,667

The Unsecured Convertible Note bears interest at the rate of 10% (which will increase to 18% upon and during the continuance of an event of default) per annum, compounding on a daily basis. All principal and accrued interest on the Unsecured Convertible Note is due on the second-year anniversary of the Unsecured Convertible Note's issuance. During the year ended December 31, 2019, the Company made principal payments of $1.5 million on the Unsecured Convertible Note.

At any time after the six-month anniversary of the issuance of the Unsecured Convertible Note, (i) if the average volume weighted-average price over twenty trading dates exceeds $10.00 per share, the Company may generally require that the Unsecured Convertible Note convert into shares of its common stock at the $3.25 (as adjusted) conversion price, and (ii) the Convertible Noteholder may elect to require all or a portion of the Unsecured Convertible Note be redeemed by the Company. If the Convertible Noteholder requires a redemption, the Company, at its discretion, may pay the redeemed portion of the Unsecured Convertible Note in cash or in the Company's common stock at a conversion rate equal to the lesser of (i) the $3.25 (as adjusted) conversion rate or (ii) 80% of the average of the five lowest volume weighted-average price of the Company's Common Stock over the preceding twenty trading days. The Convertible Noteholder may not redeem more than $500,000 per calendar month during the period between the six-month anniversary of the date of issuance until the first-year anniversary of the date of issuance and $750,000 per calendar month thereafter. The obligation or right of the Company to deliver its shares upon the conversion or redemption of the Unsecured Convertible Note is subject to a 19.99% cap and subject to a floor price trading price of $3.25 (unless waived by the Company). Any amounts redeemed once the cap is reached or if the market price is less than the $3.25 floor price must be paid in cash.

If there is an Event of Default under the Unsecured Convertible Note, the Convertible Noteholder may accelerate the Company's obligations or elect to increase the outstanding obligations under the Unsecured Convertible Note. The amount of the increase ranges from 5% to 15% depending on the type of default (as defined in the Unsecured Convertible Note). In addition, the Unsecured Convertible Note obligations will be increased if there are delays in the Company's delivery requirements for the shares or cash issuable upon the conversion or redemption of the Unsecured Convertible Note in certain circumstances.

If the Company issues convertible debt in the future with any terms, including conversion terms, that are more favorable to the terms of the Unsecured Convertible Note, the Convertible Noteholder may elect to incorporate the more favorable terms into the Unsecured Convertible Note.

NOTE 7: LICENSE AGREEMENTS

During 2016, the Company entered into a license agreement (the "Alba License") with Alba Therapeutics Corporation ("Alba") to obtain the rights to certain intellectual property relating to larazotide acetate and related compounds. The Company's initial area of focus for these assets relates to the treatment of celiac disease. These assets are now referred to as INN-202 by the Company.

Upon execution of the Alba License, the Company paid Alba a non-refundable license fee of $0.5 million. In addition, the Company is required to make milestone payments to Alba upon the achievement of certain clinical and regulatory milestones totaling up to $1.5 million and payments upon regulatory approval and commercial sales of a licensed product totaling up to $150 million, which is based on sales ranging from $100 million to $1.5 billion.

Upon the Company paying Alba $2.5 million for the first commercial sale of a licensed product, the Alba License becomes perpetual and irrevocable. Upon the achievement of net sales in a year exceeding $1.5 billion, the Alba License also becomes free of milestone fees. The Alba License provides Alba with certain termination rights, including failure of the Company to use Commercially Reasonable Efforts to develop the licensed products.

During 2013, the Company entered into an exclusive license agreement with Seachaid Pharmaceuticals, Inc. (the "Seachaid Agreement") to further develop and commercialize the licensed product, the compound known as APAZA. This product is now referred to as INN-108 by the Company. The agreement shall continue in effect on a country-by-country basis, unless terminated sooner in accordance with the termination provisions of the agreement, until the expiration of the royalty term for such product and such country. The royalty term for each such product and such country shall continue until the earlier of the expiration of certain patent rights (as defined in the agreement) or the date that the sales for one or more generic equivalents makes up a certain percentage of sales in an applicable country during a calendar year.

The Company was required to make an initial, non-refundable payment under the Seachaid Agreement in the amount of $0.2 million. The agreement also calls for milestone payments totaling up to $6.0 million to be paid when certain clinical and regulatory milestones are met. There are also commercialization milestone payments ranging from $1.0 million to $2.5 million depending on net sales of the products in a single calendar year, followed by royalty payments in the single digits based on net product sales.

During 2014, the Company entered into an 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 Magnetic Resonance Cholangiopancreatography. This program is now referred to as INN-329 by the Company. As consideration for the Asset Purchase Agreement, the Company agreed to make a non-refundable cash payment on the date of the agreement and future royalty payments consisting of a percentage between five and fifteen 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) 10 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.

The Company incurred milestone fees of approximately $0.3 million during the year ended December 31, 2019. There were no milestone or royalty fees incurred during the year ended December 31, 2018.

NOTE 8: STOCKHOLDERS' DEFICIT

The Company's authorized capital stock consists of 360 million shares of capital stock, par value $0.0001 per share, of which 350 million shares are designated as common stock and 10 million shares are designated as preferred stock.

Preferred Stock

The Company's amended and restated certificate of incorporation authorizes the Board to issue preferred stock in one or more classes or one or more series within any class from time to time. Voting powers, designations, preferences, qualifications, limitations, restrictions or other rights will be determined by the Board at that time. There were no shares of preferred stock issued and outstanding as of December 31, 2019 and 2018.

Common Stock

The holders of the Company's common stock (i) have equal ratable rights to dividends from funds legally available, therefore, when, as and if declared by the Board; (ii) are entitled to share in all the Company's assets available for distribution to holders of common stock upon liquidation, dissolution or winding up of the Company's affairs; (iii) do not have preemptive, subscription or conversion rights and there are no redemption or sinking fund provisions or rights; and (iv) are entitled to one non-cumulative vote per share on all matters on which stockholders may vote.

There were 39,477,667 and 26,088,820 shares of common stock outstanding as of December 31, 2019 and 2018, respectively. The Company had reserved shares of common stock for future issuance as follows:

	December 31,	
	2019	**2018**
Outstanding stock options	8,781,615	7,117,002
Warrants to purchase common stock	14,040,452	1,914,316
Shares issuable upon conversion of convertible debt	1,217,008	1,720,224
For possible future issuance under the Omnibus Plan	1,102,739	2,230,057
Total common shares reserved for future issuance	25,141,814	12,981,599

During the year ended December 31, 2019, the Company sold 8,499,340 shares of common stock and issued Short-Term Warrants and Long-Term Warrants to purchase up to 15,120,898 shares of common stock. On December 19, 2019, the Company and each of the purchasers of the April Warrants and Placement Agent Warrants entered into the Exchange Agreements, pursuant to which the Company agreed to issue to the purchasers an aggregate of 5,441,023 shares of Common Stock at a ratio of 1.2 Exchange Shares for each purchaser warrant in exchange for the cancellation and termination of all of the outstanding April Warrants and Placement Agent Warrants. On December 26, 2019, an aggregate of 2,994,762 warrants were exchanged for 3,593,714 shares of the Company's common stock. See Note 1—Summary of Significant Accounting Policies for further details.

On October 26, 2018, the Company entered into a common stock sales agreement with H.C. Wainwright & Co., LLC and Ladenburg Thalmann & Co. Inc. and filed a prospectus with the SEC relating to such offering. The Company previously filed a Form S-3 that became effective July 13, 2018 that included the registration of $40 million of its shares of common stock in connection with a potential ATM offering. Pursuant to the sales agreement, the Company could issue and sell shares having an aggregate gross sales price of up to $40 million and was required to pay the sales agents commissions of 3.0% of the gross sales price per share sold. During the years ended December 31, 2019 and 2018, the Company sold 705,714 and 17,576 shares under the ATM, respectively, for net proceeds of approximately $1,675,000 and $43,000, respectively. All proceeds were received as of December 31, 2019. The Company voluntarily suspended the ATM facility as of June 24, 2019. Due to suspension of the ATM facility, deferred offering costs of approximately $0.1 million were written off during the year ended December 31, 2019. Effective March 19, 2020, the Company terminated the ATM facility.

NOTE 9: SHARE-BASED COMPENSATION

Upon consummation of the Monster Merger, the Company had two stock option plans in existence, Monster's 2012 Omnibus Incentive Plan (the "Omnibus Plan") and the Innovate 2015 Stock Incentive Plan (the "Private Innovate Plan"). During 2018, the Board approved an amendment to the Omnibus Plan to, among other things, formally change the name of the Omnibus Plan to the Innovate Biopharmaceuticals, Inc. 2012 Omnibus Incentive Plan and increase the number of shares authorized for issuance under the Omnibus Plan to provide for an additional 3,000,000 shares. In addition, the shares reserved for issuance under the Omnibus Plan automatically increase on the first day of each calendar year beginning in 2019 and ending in 2022 by an amount equal to the lesser of (i) five percent of the number of shares of common stock outstanding as of December 31st of the immediately preceding calendar year or (ii) such lesser number of shares of common stock as determined by the Board (the "Evergreen Provision"). On January 1, 2019, the number of shares of common stock available under the Omnibus Plan automatically increased by 1,304,441 shares pursuant to the Evergreen Provision.

The terms of the option agreements are determined by the Board. The Company's stock options vest based on the terms in the stock option agreements and typically vest over a period of three or four years. These stock options typically have a maximum term of ten years.

Private Innovate Plan

As of December 31, 2019, there were 6,063,745 stock options outstanding under the Private Innovate Plan. Following completion of the Monster Merger, the Company has not issued, and does not intend to issue, any additional awards from the Private Innovate Plan.

The range of assumptions used in estimating the fair value of the options granted or re-measured under the Private Innovate Plan using the Black-Scholes option pricing model for the periods presented were as follows:

	Year Ended December 31,	
	2019	**2018**
Expected dividend yield	0%	0%
Expected stock-price volatility	67%	66% - 72%
Risk-free interest rate	2.6%	2.6% - 3.1%
Expected term of options (in years)	8.2 - 8.7	8.2 - 9.9

The following table summarizes stock option activity under the Private Innovate Plan:

	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2018	6,340,871	$ 1.53	$ 4,978,205	7.7
Options granted	—	—		—
Options forfeited	(177,047)	2.08		—
Options exercised	(100,079)	0.30		—
Outstanding at December 31, 2019	6,063,745	1.53	496,275	5.4
Exercisable at December 31, 2019	5,672,827	1.49	496,275	5.3
Vested and expected to vest at December 31, 2019	6,052,384	$ 1.53	$ 496,275	5.4

There were no options granted under the Private Innovate Plan during the years ended December 31, 2019 and 2018. The total intrinsic value of options exercised was approximately $81,000 and $378,000 during the years ended December 31, 2019 and 2018, respectively.

The total fair value of stock option awards vested during the years ended December 31, 2019 and 2018 under the Private Innovate Plan was approximately $578,000 and $702,000, respectively. As of December 31, 2019, there was approximately $0.5 million of total unrecognized compensation cost related to unvested stock-based compensation arrangements under the Private Innovate Plan, which is expected to be recognized over a weighted-average period of 1.3 years.

The Private Innovate Plan provides for accelerated vesting under certain change-of-control transactions, if approved by the Board.

During the year ended December 31, 2019, the compensation committee approved the extension of the exercise periods of certain option holders' vested options for an additional eighteen months. During the year ended December 31, 2019, the Company recognized additional compensation expense of $0.4 million associated with the modification of approximately 1.8 million options.

Omnibus Plan

As of December 31, 2019, there were options to purchase 2,717,870 shares of Innovate common stock outstanding under the Omnibus Plan and 1,102,739 shares available for future grants under the Omnibus Plan.

The range of assumptions used in estimating the fair value of the options granted or re-measured under the Omnibus Plan using the Black-Scholes option pricing model for the periods presented were as follows:

	Year Ended December 31,	
	2019	2018
Expected dividend yield	0%	0%
Expected stock-price volatility	67% - 72%	65% - 73%
Risk-free interest rate	1.5% - 2.7%	2.7% - 3.1%
Expected term of options (in years)	5.0 - 10.0	5.0 - 10.0

The following table summarizes stock option activity under the Omnibus Plan:

	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2018	776,131	$ 5.79	$ —	7.40
Options granted	2,366,344	1.33		
Options forfeited	(424,605)	6.02		
Options exercised	—	—		
Outstanding at December 31, 2019	2,717,870	1.87	—	9.4
Exercisable at December 31, 2019	1,444,501	2.05	—	9.3
Vested and expected to vest at December 31, 2019	2,619,282	$ 1.86	$ —	9.4

The weighted-average grant date fair value of options granted under the Omnibus Plan was $0.71 and $3.76 during the years ended December 31, 2019 and 2018, respectively.

The total fair value of stock option awards vested under the Omnibus Plan was approximately $1,227,000 and $1,032,000 during the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, there was approximately $1.2 million of total unrecognized compensation cost related to unvested stock-based compensation arrangements under the Omnibus Plan. This cost is expected to be recognized over a weighted-average period of 2.7 years.

The Omnibus Plan provides for accelerated vesting under certain change-of-control transactions, if approved by the Board.

During the year ended December 31, 2019, the Board approved grants of 490,000 RSUs. 390,000 of the RSUs vested immediately on the date of grant; the remaining 100,000 RSUs vest 50% on the date of grant and the remainder pro-rata over six months following the date of grant. The weighted-average fair value of RSUs granted during the year ended December 31, 2019 was $1.44 and the Company recognized share-based compensation expense for the RSUs of approximately $705,000 during the year ended December 31, 2019. There were no RSUs granted during the year ended December 31, 2018.

Total share-based compensation expense recognized in the accompanying statements of operations and comprehensive loss was as follows:

	Year Ended December 31,	
	2019	2018
Research and development	$ 908,000	$ 2,445,000
General and administrative	1,963,000	1,360,000
Total share-based compensation	$ 2,871,000	$ 3,805,000

NOTE 10: INCOME TAXES

No provision for federal and state income tax expense has been recorded for the years ended December 31, 2019 and 2018 due to the valuation allowance recorded against the net deferred tax asset and recurring losses.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company’s deferred tax assets and deferred tax liabilities are as follows:

	December 31,	
	2019	2018
Tax loss and contribution carryforwards	$ 9,857,000	$ 4,336,800
Tax credits	723,800	224,900
Share-based compensation	2,805,700	2,377,400
Intangible assets	1,716,300	1,677,600
Accrued expenses	122,500	151,800
Legal fees	111,800	—
Other	60,100	4,500
Valuation allowance	(15,397,200)	(8,773,000)
Total deferred tax assets, noncurrent	$ —	$ —

The Company has established a valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets. During the years ended December 31, 2019 and 2018, the valuation allowance increased by $6,624,200 and $4,921,000, respectively.

The reasons for the difference between actual income tax expense (benefit) for the years ended December 31, 2019 and 2018, and the amount computed by applying the statutory federal income tax rate to losses before income tax (benefit) are as follows:

	2019		2018	
	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings
Income tax benefit at statutory rate	$ (5,680,200)	21.0 %	$ (5,074,100)	21.0 %
State income taxes, net of federal tax benefit	(534,200)	2.0 %	(477,200)	2.0 %
Non-deductible expenses	89,100	(0.3)%	333,600	(1.4)%
Credits	(540,200)	2.0 %	(224,900)	0.9 %
Change in state tax rate	—	— %	(82,300)	0.3 %
Other	41,300	(0.2)%	603,900	(2.5)%
Change in valuation allowance	6,624,200	(24.5)%	4,921,000	(20.3)%
Income tax benefit	$ —	— %	$ —	— %

As of December 31, 2019, the Company had net operating loss carryforwards for federal and state income tax purposes of $42,944,800 and $42,349,200, respectively. Federal loss carryforwards of $3,551,900 begin to expire in 2034 and $39,392,900 of the federal losses carryforward indefinitely. The state loss carryforwards begin to expire in 2029. As of December 31, 2018, the Company had contribution carryforwards of $10,300, which begin to expire in 2021. In addition, the Company has federal research and development credits of $723,800 which begin to expire in 2038.

The Internal Revenue Code of 1986, as amended, contains provisions which limit the ability to utilize the net operating loss and tax credit carryforwards in the case of certain events, including significant changes in ownership interests. If the Company's net operating loss and tax credit carryforwards are limited, and the Company has taxable income which exceeds the permissible yearly net operating loss and tax credit carryforwards, the Company would incur a federal income tax liability even though net operating loss and tax credit carryforwards would be available in future years.

As of December 31, 2019 and 2018, the Company had no unrecognized tax benefits and does not anticipate a significant change in total unrecognized tax benefits within the next 12 months.

The Company is subject to United States federal income tax and income tax in multiple state jurisdictions. The Company has analyzed its filing positions in all federal and state jurisdictions where it is required to file income tax returns, as well as open tax years in these jurisdictions. The Company is subject to United States federal, state and local tax examinations by tax authorities for all years of operation. No income tax returns are under examination by taxing authorities at this time.

The Company's policy for recording interest and penalties is to record them as a component of interest expense and general and administrative expenses, respectively. During December 31, 2019 and 2018, the Company did not record any interest and penalties related to uncertain tax positions.

NOTE 11: COMMITMENTS AND CONTINGENCIES

Clinical Trial Agreement

From time to time, the Company enters into agreements with contract research organizations and other service providers. In August 2018, the Company entered into such an agreement for its planned Phase 3 trial for the treatment of celiac disease. Under this agreement, the Company expects to pay approximately $1.1 million for data management over the course of the Phase 3 celiac disease trial for data management and biostatistics services.

Employment Agreements

Prior to March 11, 2018, the Company was party to employment agreements with certain executives of the Company. Under the terms of these agreements, the Company agreed to pay the executives certain payments upon the achievement of financial milestone events. These milestone events were based on total debt or equity funding received by the Company. During the year ended December 31, 2018, financial milestone events were achieved through the Monster Merger and Equity Issuance events and the Company paid these executives approximately $1.1 million in accordance with the agreements.

The Company has entered into amended and restated executive employment agreements with the executives and new executive employment agreements with certain new executives (the "Executive Employment Agreements"). The Executive Employment Agreements provide an annual base salary and the opportunity to participate in the Company's equity compensation, employee benefit and bonus plans once they are established and approved by the Board. The Executive Employment Agreements contain severance provisions if the executives are terminated under certain conditions that would provide the executive with up to 12 months of their base salary and up to 12 months of continuation of health insurance benefits.

In November 2018 and February 2019, the Company entered into separation and general release agreements with two former executives of the Company that included separation benefits consistent with each former executive's employment agreement. The Company recognized severance expense totaling $300,000 during the year ended December 31, 2019, which is being paid in equal installments over 12 months beginning February 2019. The Company recognized severance expense totaling $320,000 during the year ended December 31, 2018. The remaining severance obligation in respect of the two former executives is $41,000 as of December 31, 2019, which is included in accrued expenses on the accompanying balance sheet.

Office Lease

In October 2017, the Company entered into a three-year lease for office space that expires on September 30, 2020. Base annual rent is $60,000, or $5,000 per month. Monthly payments of $5,000 are due and payable over the 24-month term. A security deposit of $5,000 was paid in October 2017. The lease contains a two-year renewal option.

Effective January 1, 2019, the Company adopted ASC 842 using the transition approach described in Note 1—Summary of Significant Accounting Policies. On the adoption date, the Company estimated the present value of the lease payments over the remaining term of the lease using a discount rate of 12%, which represented the Company's estimated incremental borrowing rate. The two-year renewal option was excluded from the lease payments as the Company concluded the exercise of this option was not considered reasonably certain.

Operating lease cost under ASC 842 was $60,000 for the year ended December 31, 2019 and is included in general and administrative expenses on the accompanying statement of operations and comprehensive loss. Lease expense under ASC 840 was $60,000 for the year ended December 31, 2018 and is included in general and administrative expenses on the accompanying statements of operations and comprehensive loss. The total cash paid for amounts included in the measurement of the operating lease liability and reported within operating activities was less than $0.1 million during the year ended December 31, 2019.

Future minimum payments under the Company's lease liability were as follows:

Year ended December 31,	Operating Leases
2020	$ 45,000
Total lease payment	45,000
Less: imputed interest	(2,170)
Total	$ 42,830

Legal

In prior periods, the Company reported a claim filed in the Superior Court of the State of Delaware regarding a former consultant of the Company who was compensated in cash and stock options for his services, demanding damages of up to approximately $3.6 million plus punitive damages in connection with a delay in such consultant's ability and timing to exercise options and sell shares of the Company's common stock related to past consulting services. The Company strongly denies any wrongdoing alleged in the threatened litigation and firmly believes the allegations in the complaint are entirely without merit and intends to defend against them vigorously. On October 15, 2019, the court granted the Company's motion to dismiss and concluded the plaintiff failed to sufficiently assert claims. Briefing on the plaintiff's appeal was completed on February 21, 2020. No decision has been rendered yet by the Delaware Supreme Court. The Company is unable to estimate the amount of a potential loss or range of potential loss, if any.

From time to time, the Company could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. Periodically, the Company reviews the status of significant matters, if any exist, and assesses its potential financial exposure. If the potential loss from any claim or legal claim is considered probable and the amount can be estimated, the Company accrues a liability for the estimated loss. Legal proceedings are subject to uncertainties, and the outcomes are difficult to predict; therefore, accruals are based on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and litigation.

NOTE 12: SUBSEQUENT EVENTS

Warrant Exchange

During the first quarter of 2020, an aggregate of 1,539,424 warrants were exchanged for 1,847,309 shares of the Company's common stock pursuant to the Exchange Agreements further described in Note 1—Summary of Significant Accounting Policies. Subsequent to the exchange, there were no April Warrants or Placement Agent Warrants outstanding.

Warrant Extension and Tender Offer

Effective February 6, 2020, the Company and the holders of the Company's outstanding Short-Term Warrants amended the Short-Term Warrants to extend the exercise period of each Short-Term Warrant by six months. The Short-Term Warrants, as amended, are exercisable for up to an aggregate of 4,181,068 shares of the Company's common stock, par value $0.0001 per share, until September 18, 2020. Except as specifically amended, all terms and conditions of each Short-Term Warrant remained in full force and effect and was not affected by this amendment.

On February 12, 2020, the Company offered to amend outstanding warrants to purchase an aggregate of 12,346,631 shares of common stock (the "Original Warrants") held by holders of certain outstanding warrants (the "Offer to Amend and Exercise"). The Original Warrants of eligible holders who elect to participate in the Offer to Amend and Exercise will be amended to (i) shorten the exercise period to expire concurrently with the closing of the RDD Merger and (ii) significantly reduce the exercise price per share. The amended warrants are required to be exercised for cash, and any cashless exercise provisions in the Original Warrants have been omitted.

Additional Note

On January 10, 2020, the Company entered into an additional securities purchase agreement and unsecured convertible promissory note with the Convertible Noteholder in the principal amount of $2,750,000 (the "Additional Note"). The Convertible Noteholder may elect to convert all or a portion of the Additional Note, at any time from time to time into the Company's common stock at a conversion price of $3.25 per share, subject to adjustment for stock splits, dividends, combinations and similar events. The Company may prepay all or a portion of the Additional Note at any time for an amount equal to 115% of then outstanding obligations or the portion of the obligations we are prepaying. The purchase price of the Additional Note was $2.5 million and carries an original issuance discount of $250,000, which is included in the principal amount of the Additional Note.

The Additional Note bears interest at the rate of 10% (which will increase to 18% upon and during the continuance of an event of default) per annum, compounding on a daily basis. All principal and accrued interest on the Additional Note is due on the second anniversary of the date of the Additional Note's issuance.

At any time after the six-month anniversary of the issuance of the Additional Note, (i) if the average VWAP of the Company's common stock over twenty trading dates exceeds $10.00 per share, the Company may generally require that the Additional Note convert into share of its common stock at the $3.25 (as adjusted) conversion rate or (ii) 80% of the average of the five lowest VWAP of the Company's common stock over the preceding twenty trading days. The Convertible Noteholder may not redeem more than $500,000 per calendar month during the period between the six-month anniversary of the date of issuance until the first anniversary of the date of issuance and $750,000 per calendar month thereafter. The obligation or right of the Company to deliver its shares upon the conversion or redemption of the Additional Note is subject to a 19.99% cap and subject to a floor price of $3.25 (unless waived by the Company). Any amounts redeemed or converted once the cap is reached or if the market price is less than the $3.25 floor price must be paid in cash.

If there is an Event of Default under the Additional Note, the Convertible Noteholder may accelerate the Company's obligations or the Convertible Noteholder may elect to increase the outstanding obligations under the Additional Note. The amount of the increase ranges from 15% for certain "Major Defaults," 10% for failure to obtain the Convertible Noteholder's approval for certain equity issuances with anti-dilution, price reset or variable pricing features of less than $2,500,000, and 5% for certain "Minor Defaults." In addition, the Additional Note obligations will be increased if there are delays in the Company's delivery requirements for the shares or cash issuable upon the conversion or redemption of the Additional Note in certain circumstances.

If the Company issues convertible debt in the future with any terms, including conversion terms, that are more favorable to the terms of the Additional Note, the Convertible Noteholder may elect to incorporate the more favorable terms into the Additional Note.

Termination of ATM Facility

Effective March 19, 2020, the Company terminated the ATM facility. See Note 1—Summary of Significant Accounting Policies and Note 8—Stockholders' Deficit for further detail on the ATM facility.

Risks Related to COVID-19 Pandemic

The recent outbreak of COVID-19 originated in Wuhan, China, in December 2019 and has since spread to multiple countries, including the United States and several European countries. On March 11, 2020, the World Health Organization declared the outbreak a pandemic. The COVID-19 pandemic is affecting the United States and global economies and may affect the Company's operations and those of third parties on which the Company relies, including by causing disruptions in the supply of the Company's product candidates and the conduct of current and future clinical trials. In addition, the COVID-19 pandemic may affect the operations of the Food and Drug Administration and other health authorities, which could result in delays of reviews and approvals, including with respect to the Company's product candidates. The evolving COVID-19 pandemic is also likely to directly or indirectly impact the pace of enrollment in the Company's Phase 3 registration trials for INN-202 for at least the next several months and possibly longer as patients may avoid or may not be able to travel to healthcare facilities and physicians' offices unless due to a health emergency. Such facilities and offices may also be required to focus limited resources on non-clinical trial matters, including treatment of COVID-19 patients, and may not be available, in whole or in part, for clinical trial services related to INN-202 or the Company's other product candidates. Additionally, while the potential economic impact brought by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital, which could negatively impact the Company's short-term and long-term liquidity and the Company's and RDD's ability to complete the RDD Merger and RDD Merger Financing on a timely basis or at all. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. The Company does not yet know the full extent of potential delays or impacts on its business, financing or clinical trial activities or on healthcare systems or the global economy as a whole. However, these effects could have a material impact on the Company's liquidity, capital resources, operations and business and those of the third parties on which we rely.

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Innovate Biopharmaceuticals, Inc. ("we," "us," "our," the "Company") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our common stock.

The following description of our common stock is a summary, does not purport to be complete and is subject to, and is qualified in its entirety by reference to, the applicable provisions of the General Corporation Law of the State of Delaware (the "DGCL"), our amended and restated certificate of incorporation ("Certificate of Incorporation"), and our amended and restated bylaws ("Bylaws"). Copies of our Certificate of Incorporation and our Bylaws are incorporated by reference as exhibits to the Annual Report on Form 10-K of which this Exhibit 4.2 is a part. We encourage you to read our Certificate of Incorporation, our Bylaws and the applicable provisions of the DGCL for additional information.

General

The Company's authorized capital stock consists of 360,000,000 shares of capital stock, par value $0.0001 per share, of which 350,000,000 shares are common stock, par value $0.0001 per share, and 10,000,000 are preferred stock, par value $0.0001 per share.

Common Stock

The holders of our common stock (i) have equal ratable rights to dividends from funds legally available therefore when, as and if declared by our Board of Directors; (ii) are entitled to share in all of our assets available for distribution to holders of common stock upon liquidation, dissolution or winding up of our affairs; (iii) do not have preemptive, subscription or conversion rights and no redemption or sinking fund provisions or rights; and (iv) are entitled to one non-cumulative vote per share on all matters on which stockholders may vote, meaning that the holders of 50.1% of our outstanding shares of common stock, voting for the election of directors, can elect all of the directors to be elected, and in such event, the holders of the remaining shares will not be able to elect any of our directors.

Preferred Stock

The Certificate of Incorporation authorizes our Board of Directors to issue preferred stock in one or more classes or one or more series within any class from time to time. The voting powers, designations, preferences, qualifications, limitations, restrictions and other rights of our preferred stock will be determined by our Board of Directors at that time.

Anti-Takeover Effects of Our Certificate of Incorporation and Bylaws and Certain Provisions of the DGCL

General. Our Certificate of Incorporation contains provisions that could have an anti-takeover effect, including provisions that:

- grant our Board of Directors the authority to issue up to 10,000,000 shares of preferred stock and fix the price, rights, preferences, privileges and restrictions of such preferred stock without any further vote or action by our stockholders;
- provide for a classified board of directors;
- provide that vacancies on the board of directors 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;
- prohibit director removal without cause and only allow removal with cause, and allow amendment of certain provisions of our Certificate of Incorporation and our Bylaws only, in the case of such removal with cause or amendment, by the vote of the holders of at least two-thirds of all then-outstanding shares of our common stock;
- grant our board of directors the exclusive authority to increase or decrease the size of the board of directors;

- 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; and
- authorize our board of directors, by a majority vote, to amend the Bylaws.

Our Bylaws also contain provisions that could have an anti-takeover effect, including provisions that require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

Exclusive Forum. Unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Company, (ii) any action asserting a claim of breach of fiduciary duty owed by, or other wrongdoing by, any director, officer, employee or agent of the Company to the Company or our stockholders, creditors or other constituents, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our Certificate of Incorporation or our Bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our Certificate of Incorporation or Bylaws or (v) any action asserting a claim governed by the internal affairs doctrine; in each case, subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein; provided that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Although our Certificate of Incorporation and our Bylaws include these provisions, it is possible that a court could rule that such provisions are inapplicable or unenforceable.

DGCL Section 203. We are subject to the anti-takeover provisions of Section 203 of the DGCL, 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 common stock.

Listing on the Nasdaq Capital Market

Our common stock is listed on the Nasdaq Capital Market under the symbol “INNT.”

Exhibit 10.23

EXECUTIVE EMPLOYMENT AGREEMENT

THIS EXECUTIVE EMPLOYMENT AGREEMENT (the "**Agreement**"), is entered into as of February 15, 2019 (the "**Effective Date**") by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "**Company**"), and Patrick H. Griffin, MD (the "**Executive**"). Throughout the remainder of the Agreement, the Company and Executive may be individually referred to as a 'party" or collectively referred to as "the parties."

W I T N E S S E T H:

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 February 20, 2019, the Company hereby employs the Executive and the Executive hereby accepts employment as the Chief Medical Officer ("**CMO**") 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 November 27, 2018, between the Parties shall terminate, except that Executive's obligations under Section 6 thereof shall survive such termination.

2. Duties.

(a) The Executive shall faithfully perform all duties of the Company related to the position held by the Executive, including but not limited to all duties set forth in this Agreement and all additional duties that are prescribed from time to time by the Board, the CEO and/or the Executive Chairman ("**EC**"), provided that any inconsistencies between instructions shall be resolved by the CEO, and in all cases such duties shall be consistent with the position of a Chief Medical Officer of a publicly traded company having similar characteristics to the Company. The Executive shall devote substantially all of the Executive's business time to the performance of the Executive's duties and responsibilities on behalf of the Company; provided, however, that it is understood that Executive will continue to provide services to Synergy Pharmaceuticals, Inc. 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 in all material respects with all applicable written Company policies, standards, rules and regulations (the "**Company Policies**") and all government laws, rules and

regulations applicable to the Company's business 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 shall work remotely from his residence in New York, New York, subject to reasonable business travel.

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 tax withholdings):

(a) Base Salary. Executive shall be paid an annual salary in the amount of $375,000 (less applicable tax withholdings), which shall be payable in accordance with the then-current payroll schedule of the Company (the "**Base Salary**"). The Executive's Base Salary will be reviewed periodically and may be increased from time to time by the Company at its discretion.

(b) Target Performance Bonus. Executive shall be eligible to receive a bonus in the amount of $75,000 (less applicable tax withholdings) if the Phase 3 clinical trial for INN-202 progresses with at least one patient being administered a dose of INN-202 (the "Target Event"). Executive will be paid the bonus within thirty (30) days following the occurrence of the Target Event.

(c) Annual Performance 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, based on a target of 25% to 50% of Executive's Base Salary. 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 and applicable to executives at Executive's level. Any bonus earned hereunder shall be paid no later than 2-1/2 months after the end of the calendar year in which it is earned. For calendar year 2018, Executive's bonus shall be prorated to reflect the portion of such year that Executive was actually retained by the Company (including, without limitation, as a consultant). Except as provided in Section 5(c)(ii), Executive must be employed as of December 31 of any calendar year to be eligible for a bonus under this Section 4(c).

(d) Equity. Executive shall be eligible to participate in any equity compensation plan or similar program adopted by the Company 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 and shall be subject to the terms and conditions of any plan or program adopted or approved by the Board, and the applicable award agreement. On or promptly after the Effective Date, the Company will make an initial grant to Executive of 500,000 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 and shall be subject to terms and conditions to be imposed by the Board under the Company's plans, programs or applicable award agreement, to include, among other things, vesting on a monthly

basis over a four (4) year period conditioned upon continued employment with the Company, with 25% of such grant vesting as of the effective date of such grant. In addition, on or promptly after the Effective Date, the Company will make an initial grant to Executive of 100,000 restricted stock units ("**RSUs**"). Such RSU grant will be effective when made and shall be subject to terms and conditions to be imposed by the Board under its plans, programs or applicable award agreement, to include, among other things, vesting on a monthly basis over a one (1) year period conditioned upon continued employment with the Company, with 25% of such grant vesting as of the effective date of such grant.

(e) 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.

(f) 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.

(g) 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.

(h) Reimbursement of Attorneys' Fees. The Company will reimburse Executive for his reasonable attorneys' fees incurred in connection with this Agreement, up to a maximum amount of Ten Thousand and 00/100 Dollars ($10,000). Such amount will be paid within thirty (30) days of Executive' submission of acceptable documentation of such fees, but in no event later than May 31, 2019. Executive shall be solely responsible for all taxes, if any, associated with this reimbursement.

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 materially reduced 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 outside of the borough of Manhattan in New York, New York. 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 and deliberate failure of the Executive to diligently perform the Executive's duties for the Company; 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) that results (or would be reasonably likely to result) in material harm to the Company, or Executive's material breach of the Proprietary Information Agreement (as defined herein) or any other similar written agreement between Executive and the Company regarding confidentiality, intellectual property rights, non-competition or non-solicitation; provided, however, that the Company must first provide Executive with written notice of the grounds under this Section 5(b)(iv)(B) and a period of ten (10) business days in which to cure such grounds;

C. Any material failure to comply with applicable material Company Policies, government laws, rules and regulations applicable to the Company's business and/or directives of the Board consistent with Executive's position; provided, however, that the Company must first provide Executive with written notice of the grounds under this Section 5(b)(iv)(C) and a period of ten (10) business days in which to cure such grounds;

D. The Executive's use of illegal drugs or any illegal substance, or the Executive's use of alcohol, in any case, in any manner that materially interferes with the performance of the Executive's duties under this Agreement; provided, however, that the Company must first provide Executive with written notice of the grounds under this Section 5(b)(iv)(D) and a period of ten (10) business days in which to cure such grounds;

E. Any action taken by the Executive in bad faith which is materially detrimental to the interest and well-being of the Company, including, without limitation, material harm to its reputation; provided, however, that the Company must first provide Executive with written notice of the grounds under this Section 5(b)(iv)(E) and a period of ten (10) business days in which to cure such grounds; or

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; provided, however, that the Company must first provide Executive with written notice of the grounds under this Section 5(b)(iv)(F) and a period of ten (10) business days in which to cure such grounds.

(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, including any earned but unpaid bonus under Section 4(b), all of 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 (provided that in the case of a termination by the Company pursuant to paragraph 5(b)(ii) or (iii), Executive (or his estate, as applicable) shall be entitled to receive payment of any bonus earned in the year prior to the year of termination but that is unpaid as of the termination date, to be paid at the same time

such bonus would have been paid if no such termination had occurred (the "**Earned But Unpaid Bonus**")).

(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 agreement in the form attached hereto as Exhibit A 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 tax withholdings) payable in installments during the one year period immediately following the termination date 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 (with the first payment to include a catchup for any amounts that would have been paid had the Release been effective on the termination date); (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) 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); (3) the Earned But Unpaid Bonus (if any), to be paid at the same time such bonus would have been paid if no such termination had occurred; (4) all stock options, restricted stock unit and other stock-based awards granted to Executive that were scheduled to vest during the 12 month period immediately following Executive's termination of employment shall become immediately vested and exercisable (if applicable) and with respect to restricted stock units and similar awards, including the RSUs described in Section 4(d) herein, shall be settled within 30 days after the termination date; and (5) Executive shall be entitled to receive his annual bonus for the year of termination as determined by the Board, pro-rated based on the number of days that Executive was employed by the Company during the year in which such termination of employment occurred (to be paid at the same time such bonus would have been paid if no such termination had occurred).

(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. 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 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. Executive will be entitled to indemnification under the Company's Directors and Officers insurance policy during his employment with the Company and for the six year period thereafter on terms no less favorable than any other officer of the Company.

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

If to the Company,

Innovate Biopharmaceuticals, Inc.
8480 Honeycutt Road, Suite 120
Raleigh, NC 27615
Attn: Kendyle Woodard
Email: *kwoodard@innovatebiopharma.com*

If to Executive:

Patrick H. Griffin, M.D.
143 Bennett Ave, #55
New York, NY 10040

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. To the extent required by Section 409A, any portion of the

severance benefits payable to Executive under Section 5(c)(ii) that are contingent on the Executive's execution and non-revocation of the Release and that could be paid in the calendar year in which Executive terminates employment or in the immediately following calendar year, depending on when the Release becomes effective shall be paid on the first payroll date in such immediately following calendar year or such later date required by Section 5(c)(ii) (with all remaining payments of such severance benefits to be paid as if no such delay had occurred).

(d) If the Executive 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.

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/ Sandeep Laumas
Sandeep Laumas, MD
Executive Chairman

By: /s/ Christopher Prior
Christopher Prior
Chief Executive Officer

PATRICK H. GRIFFIN, M.D.

/s/ Patrick H. Griffin

Exhibit A to Employment Agreement

SEPARATION AND GENERAL RELEASE AGREEMENT

THIS SEPARATION AND GENERAL RELEASE AGREEMENT (the "Agreement") is made and entered into by and between Innovate Biopharmaceuticals, Inc., a Delaware corporation (the "Company"), and Patrick H. Griffin, MD (the "Executive"). Throughout the remainder of the Agreement, the Company and Executive may be individually referred to as a 'party" or collectively referred to as "the parties."

Executive was employed as Chief Medical Officer of the Company pursuant to an employment agreement between the parties dated February 15, 2019 (the "Employment Agreement"). Executive is also a party to a Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement with the Company, dated February 15, 2019 (the "Proprietary Information Agreement").

Executive's employment terminated [without cause] [for Good Reason] as of _____. The parties wish to provide for the payment of severance benefits to Executive under his Employment Agreement as set forth in this Agreement.

Executive represents that he has carefully read this entire Agreement, understands its consequences, and voluntarily enters into it.

NOW THEREFORE, in consideration of the above and the mutual promises set forth below, Executive and the Company agree as follows:

1. SEPARATION. Executive's employment with the Company [will terminate] [terminated] as of [Date___] (the "Separation Date"). Pursuant to Section 5(d) of the Employment Agreement, as of the Separation Date, Executive no longer held any officer positions with the Company. Executive will be paid all accrued unused vacation on the first regularly scheduled payroll date which occurs at least 5 days after the Separation Date. Executive shall be paid his base salary and participate in regular benefits through the Separation Date[, and shall be paid for any earned but unpaid bonus under Section 4(b) of the Employment Agreement on the [first] [___] regular payroll date following the Separation Date]. Promptly after the Separation Date, Executive shall be reimbursed for all unreimbursed business expenses incurred by Executive while employed or engaged by the Company, such reimbursements to be provided in accordance with the Company's expense reimbursement policy. The payments and benefits described in this Section 1 are collectively referred to in this Agreement as the "Accrued Benefits."

2. SEPARATION BENEFITS. In consideration of the release of claims and other promises contained herein and on the condition that Executive fully complies with his obligations under this Agreement and the Proprietary Information Agreement, the Company will provide Executive with the following benefits as provided in Section 5(c) provided that this Agreement has become effective under Section 8 herein:

(a) Severance Pay. The Company shall pay to Executive _____Dollars ($_____) (less applicable withholdings), payable in equal

installments over a twelve (12) month period in accordance with the Company's current payroll schedule commencing on the Company's first regularly scheduled pay date following the Effective Date of this Agreement pursuant to Section 8, subject to Section 15(c), provided that the first such installment shall include a catchup for any amounts that would have been paid had this Agreement been effective as of the Separation Date.

(b) Benefits. Conditioned on Executive's eligibility for, and Executive's proper and timely election to continue health insurance benefits under COBRA after the Separation Date, reimbursement of the additional costs actually incurred by Executive for continuing such benefits at the same level in which Executive participated prior to the Separation Date for the shorter of (i) twelve (12) months following the Separation Date or (ii) until Executive obtains reasonably comparable coverage, with such reimbursements to commence on the first regular payroll date following the Effective Date of this Agreement pursuant to Section 8, subject to Section 15(c). Such reimbursements are subject to Executive providing appropriate proof of the costs for such premiums.

(c) Earned But Unpaid Bonus for Prior Calendar Year. Executive shall be paid the amount of $_____ (less applicable withholdings), as his earned but unpaid bonus for the preceding calendar year, to be paid in lump sum on or before _____, subject to Section 15(c) of this Agreement.

(d) Equity Awards. All unvested stock options, restricted stock unit and other stock-based awards granted to Executive that were scheduled to vest during the 12 month period immediately following the Separation Date shall become immediately vested and exercisable (if applicable) and with respect to restricted stock units and similar awards, including the RSUs described in Section 4(d) of the Employment Agreement, shall be settled within 30 days after the Separation Date.

(e) Bonus for Current Calendar Year. Executive shall be entitled to receive his annual bonus for the ____ calendar year, to be determined by the Board, and pro-rated based on the number of days that Executive was employed by the Company during such calendar year, to be paid in lump sum (less applicable withholdings) when such bonus would have been paid if no such termination had occurred, but in no event after March 15, ____ subject to Section 15(c) of this Agreement.

Following the Separation Date, Executive shall not be entitled to be an active participant in any medical, dental, vision, life, disability, accidental death and dismemberment insurance benefits, or any other employee benefit plans of the Company, and shall not be an active participant in the Company's 401(k) Plan (the "401(k) Plan"). For the avoidance of doubt, Executive will not be eligible to contribute to his 401(k) plan from any payments received under this Agreement after the Separation Date, except for his regular salary paid through the Separation Date. Nothing in this Agreement, however, shall be deemed to limit Executive's continuation coverage rights under COBRA or Executive's vested rights, if any, under the 401(k) Plan or any other Company plan, and the terms of those plans shall govern.

3. PROPRIETARY INFORMATION AGREEMENT. Executive is subject to the Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement, dated February __, 2019 (the "Proprietary Information Agreement"). Executive acknowledges and agrees that Executive will continue to be bound by and subject to the Proprietary Information Agreement, in accordance with its terms, and that he will forfeit all benefits under this Agreement should Executive breach such Proprietary Information Agreement

4. COOPERATION. Executive agrees that, for a period of three (3) years following the Separation Date, he will reasonably assist and reasonably cooperate with the Company in connection with the defense or prosecution of any claim that may be made against or by the Company, or in connection with any ongoing or future investigation or dispute or claim of any kind involving the Company, including any proceeding before any arbitral, administrative, judicial, legislative, or other body or agency, including testifying in any proceeding, in all cases, only to the extent such claims, investigations or proceedings are relating to services performed or required to be performed by Executive for the Company, pertinent knowledge possessed by Executive, or any act or omission by Executive. The Company shall provide reasonable compensation to Executive for his time and reimburse Executive for reasonable expenses incurred in connection with such cooperation. Executive's requirement to cooperate under this Section 4 shall not apply to any claims, actions or proceedings brought by the Company against Executive or by Executive against the Company. Notwithstanding anything contained in this Section 4 to the contrary, Executive's cooperation under this Section 4 shall be at mutually agreeable times and locations and shall not interfere with Executive's duties and responsibilities to a subsequent employer or business venture.

5. RELEASE. In consideration of the benefits conferred by this AGREEMENT, EXECUTIVE (ON BEHALF OF HIMSELF AND HIS FAMILY MEMBERS, HEIRS, ASSIGNS, EXECUTORS AND OTHER REPRESENTATIVES), RELEASES THE COMPANY AND ITS PAST, PRESENT AND FUTURE PARENTS, SUBSIDIARIES, AFFILIATES, AND ITS AND/OR THEIR PREDECESSORS, SUCCESSORS, ASSIGNS, AND ITS AND/OR THEIR PAST, PRESENT AND FUTURE OFFICERS, DIRECTORS, EXECUTIVES, OWNERS, INVESTORS, STOCKHOLDERS, ADMINISTRATORS, BUSINESS UNITS, BENEFIT PLANS (TOGETHER WITH ALL PLAN ADMINISTRATORS, TRUSTEES, FIDUCIARIES AND INSURERS) AND AGENTS (COLLECTIVELY, "RELEASEES") FROM ALL CLAIMS AND WAIVES ALL RIGHTS, KNOWN OR UNKNOWN, HE MAY HAVE OR CLAIM TO HAVE IN EACH CASE RELATING TO HIS EMPLOYMENT WITH THE COMPANY, OR HIS SEPARATION THEREFROM, arising before the execution of this Agreement by Executive, including but not limited to claims: (i) for discrimination, harassment or retaliation arising under any federal, state or local laws, or the equivalent applicable laws of a foreign country, prohibiting age (including but not limited to claims under the Age Discrimination in Employment Act of 1967 (ADEA), as amended, and the Older Worker Benefit Protection Act of 1990 (OWBPA)), sex, national origin, race, religion, disability, veteran status or other protected class discrimination, the Family and Medical Leave Act, as amended (FMLA), and/or harassment or retaliation for protected activity; (ii) for compensation, commission payments, bonus payments and/or benefits including but not limited to claims under the Fair Labor Standards Act of 1938 (FLSA), as amended, the Employee Retirement Income Security Act of 1974, as amended (ERISA), the Family and Medical Leave Act, as amended (FMLA), and similar federal, state, and local laws, or the applicable laws of any foreign

country; (iii) under federal, state or local law, or the applicable laws of any foreign country, of any nature whatsoever, including but not limited to constitutional, statutory and common law; (iv) under the Employment Agreement, or any other employment agreement, severance plan or other benefit plan; and (v) for attorneys' fees. Executive specifically waives his right to bring or participate in any class or collective action against the Company. Provided, however, that this release does not apply to claims by Executive (and Executive is not releasing any person or entity from claims relating to): (aa) for workers' compensation benefits or unemployment benefits filed with the applicable state agencies; (bb) for vested pension or retirement benefits (including under the Company's 401(k) plan) or with respect to any equity or equity-based award granted to Executive; (cc) to continuation coverage under COBRA, or equivalent applicable law; (dd) to rights that cannot lawfully be released by a private settlement agreement; (ee) to enforce, or for a breach of, this Agreement; (ff) for any payments or benefits owed to Executive under the terms of this Agreement; or (gg) for indemnification under the Employment Agreement, under the Company's bylaws or other governing documents, under any directors and officers insurance policy, under applicable law or otherwise (clauses (aa) through (gg), collectively, the "Reserved Claims"). *For the purpose of implementing a full and complete release and discharge, Executive expressly acknowledges that this Agreement is intended to include in its effect, without limitation, all claims (other than Reserved Claims) which he does not know or suspect to exist in his favor at the time of execution hereof, and that this Agreement contemplates the extinguishment of any such claim or claims.*

6. COVENANT NOT TO SUE. In consideration of the benefits offered to Executive, Executive will not sue Releasees on any of the released claims or on any matters relating to his employment arising before the execution of this Agreement other than with respect to the Reserved Claims, including but not limited to claims under the ADEA, or join as a party with others who may sue Releasees on any such claims; provided, however, this paragraph will not bar a challenge under the OWBPA to the enforceability of the waiver and release of ADEA claims set forth in this Agreement, the Reserved Claims, or where otherwise prohibited by law. If Executive does not abide by this paragraph, then (i) he will return all monies received under this Agreement (other than the Accrued Benefits) and indemnify Releasees for all expenses incurred in defending the action, and (ii) Releasees will be relieved of their obligations hereunder (other than for payment of the Accrued Benefits).

6. RIGHT TO REVIEW. The Company delivered this Agreement, containing the release language set forth in Sections 5 and 6, to Executive on _____ (the "Notification Date"), and hereby informs Executive that it desires that he have adequate time and opportunity to review and understand the consequences of entering into it. The Company advises Executive as follows: (a) Executive should consult with his attorney prior to executing this Agreement; and (b) Executive has 21 days from the Notification Date within which to consider it. Executive must return an executed copy of this Agreement to the Company on or before the 22nd day following the Notification Date. Executive acknowledges and understands that he is not required to use the entire 21-day review period and may execute and return this Agreement at any time before the 22nd day following the Notification Date. If, however, Executive does not execute and return an executed copy of this Agreement on or before the 22nd day following the Notification Date, this Agreement shall become null and void. This executed Agreement shall be returned to: _____

_____.

7. REVOCATION. Executive may revoke the Agreement during the seven (7) day period immediately following his execution of it. This Agreement will not become effective or enforceable until the revocation period has expired (the "Effective Date"). To revoke this Agreement, a written notice of revocation must be delivered to: _____ _____.

8. AGENCY CHARGES/INVESTIGATIONS. Nothing in this Agreement prohibits or prevents Executive from filing a charge with or participating, testifying, or assisting in any investigation, hearing, whistleblower proceeding or other proceeding before any federal, state, or local government agency (e.g. EEOC, NLRB, SEC., etc.) (each, a "Government Agency"), nor does anything in this Agreement preclude, prohibit, or otherwise limit, in any way, Executive's rights and abilities to contact, communicate with, report matters to, or otherwise participate in any whistleblower program administered by any such agencies. Executive further understands that this Agreement does not limit Executive's or the Company's ability to communicate with any Government Agency or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency in connection with reporting a possible securities law violation, or other violation of law, without notice to the Company. Nothing in this Agreement or any other agreement limits Executive's right to receive an award for information provided to any Government Agency/SEC staff.

9. NONDISPARAGEMENT. Executive agrees that he shall not at any time make, publish or communicate to any person or entity or in any public forum any defamatory or disparaging remarks, comments or statements concerning the Company, or any of its employees or officers or suppliers. The foregoing restrictions will not apply to any statements that are made truthfully in response to a subpoena or other compulsory legal process, or as permitted by Section 9 of this Agreement. The Company agrees that none of the members of the Board of Directors or the current officers of the Company will make statements about Executive that are disparaging, defaming or derogatory; provided, however, that nothing in this Section 10 will prevent the Company or Executive from providing information requested by subpoena, court order, regulation, law, in response to a request from a government agency, or in response to a request from an insurance company, investor or other business. Additionally, nothing in this Section 10 shall prohibit truthful statements made to defend or prosecute any legal claim.

10. DISCLAIMER OF LIABILITY. Nothing in this Agreement is to be construed as either an admission of liability or admission of wrongdoing on the part of either party, each of which denies any liabilities or wrongdoing on its part.

11. 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, including but not limited to the ADEA and the OWBPA ("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.

12. ENTIRE AGREEMENT. Except as expressly provided herein, or in the Proprietary Information Agreement, this Agreement: (i) supersedes and cancels all other understandings and agreements, oral or written, with respect to Executive's employment with the Company; (ii) supersedes all other understandings and agreements, oral or written, between the parties with respect to the subject matter of this Agreement; and (iii) constitutes the sole agreement between the parties with respect to this subject matter. Each party acknowledges that: (i) no representations, inducements, promises or agreements, oral or written, have been made by any party or by anyone acting on behalf of any party, which are not embodied in this Agreement; and (ii) no agreement, statement or promise not contained in this Agreement shall be valid. No change or modification of this Agreement shall be valid or binding upon the parties unless such change or modification is in writing and is signed by the parties.

13. SEVERABILITY; SEPARATE AND INDEPENDENT COVENANTS. If any portion, provision, or part of this Agreement is held, determined, or adjudicated by any court of competent jurisdiction to be invalid, unenforceable, void, or voidable for any reason whatsoever, each such portion, provision, or part shall be severed from the remaining portions, provisions, or parts of this Agreement, and such determination or adjudication shall not affect the validity or enforceability of such remaining portions, provisions, or parts.

14. SECTION 409A OF THE INTERNAL REVENUE CODE.

(a) Parties' Intent. The parties intend that all payments or benefits hereunder shall either qualify for an exemption from or comply with the applicable rules governing non-qualified deferred compensation under Section 409A of the Internal Revenue Code of 1986, as amended (the "Code"), and the regulations thereunder (collectively, "Section 409A") and all provisions of this Agreement shall be construed in a manner consistent with such intention. If any provision of this Agreement (or of any award of compensation, including equity compensation or benefits) would cause Executive to incur any additional tax or interest under Section 409A, the Company shall, upon the specific request of Executive, use its reasonable business efforts to in good faith reform such provision to be exempt from, or comply with, Code Section 409A; provided, that to the maximum extent practicable, the original intent and economic benefit to Executive and the Company of the applicable provision shall be maintained, and the Company shall have no obligation to make any changes that could create any material additional economic cost or loss of material benefit to the Company. Notwithstanding the foregoing, the Company shall have no liability with regard to any failure to comply with Section 409A, provided that the Company acted in good faith and in a prudent manner to comply with Section 409A. Sections 14(c) and 14(d) of the Employment Agreement are incorporated herein by reference.

(b) Separation from Service. A termination of employment or separation from service shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits that constitute nonqualified deferred compensation within the meaning of Section 409A upon or following a termination of employment or separation from service unless such termination also constitutes a "Separation from Service" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment," "separation from service" or like terms shall mean Separation from Service.

(c) Delayed Distribution to Specified Employees. Section 14(d) of the Employment Agreement is hereby incorporated herein by reference (the "Severance Benefits" shall mean the payments and benefits set forth in Section 2 of this Agreement).

(d) Installment Payments. All payments made under this Agreement shall be deemed to be a 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.

16. OTHER TAXES. Executive shall have sole responsibility for the payment of any and all income taxes and/or excise taxes arising from or due on account of any payment made or benefit provided by the Company under this Agreement.

17. COUNTERPARTS. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which taken together shall constitute one and the same instrument. Any party hereto may execute this Agreement by signing any such counterpart.

18. WAIVER OF BREACH. 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.

(Signature Page Follows)

IN WITNESS WHEREOF, the parties have entered into this Agreement as of the day and year written below.

INNOVATE BIOPHARMACEUTICALS, INC.

By: _____

Name: _____

Title: _____

Date: _____

PATRICK H. GRIFFIN, M.D.

By: _____

Date: _____

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-215406, 333-228830, 333-228828 and 333-234598 on Form S-8 and Registration Statement No. 333-223669 and 333-231584 on Form S-3 of our report dated March 20, 2020, (which includes an explanatory paragraph relating to the existence of substantial doubt about the Company's ability to continue as a going concern) relating to the financial statements of Innovate Biopharmaceuticals, Inc., as of and for the years ended December 31, 2019 and 2018, included in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ Mayer Hoffman McCann P.C.

Orange County, California
March 20, 2020

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Sandeep Laumas, 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/ Sandeep Laumas

March 20, 2020

Sandeep Laumas
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Edward J. Sitar, 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/ Edward J. Sitar

March 20, 2020

Edward J. Sitar
Chief 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, Sandeep Laumas, 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, 2019 (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.

March 20, 2020

/s/ Sandeep Laumas

Sandeep Laumas
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, Edward J. Sitar, Chief 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, 2019 (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.

March 20, 2020

/s/ Edward J. Sitar

Edward J. Sitar
Chief 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.