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, 2021
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**

9 METERS BIOPHARMA, 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	NMTR	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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $274.9 million (based on the last reported closing sale price on the Nasdaq Capital Market on that date of $1.10 per share).

As of March 18, 2022, the registrant had 258,235,418 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, our need for substantial additional funding; the lengthy, expensive and uncertain nature of the clinical trial process; potential delays in commencement and completion of clinical studies; risks related to our limited operating history; 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; our ability to obtain and maintain effective intellectual property protection; the impact of COVID-19; and other risks described 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.

NOTES

Unless the context indicates otherwise, references in this Annual Report on Form 10-K to "9 Meters", "Company", "we", "us" and "our" refer to 9 Meters Biopharma, Inc. and its subsidiaries. In May 2020 we changed the name of our company from Innovate Biopharmaceuticals, Inc. to 9 Meters Biopharma, Inc. Accordingly, any reference to Innovate Biopharmaceuticals, Inc. in the documents incorporated by reference means 9 Meters Biopharma, Inc.

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 or incorporated by reference in this prospectus supplement or the accompanying prospectus, 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.

RISK FACTOR SUMMARY

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled “Risk Factors”, together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.

Risks Related to Our Capital Requirements and Financial Condition

- We have a limited operating history and have incurred significant losses since inception and expect that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.
- Our auditor has expressed substantial doubt about our ability to continue as a going concern.
- We will require substantial additional financing for further development of our product candidates.

Risks Related to Our Business Strategy and Operations

- We are substantially dependent upon the clinical, regulatory and commercial success of our product candidates.
- The COVID-19 pandemic has and may continue to materially and adversely affect our business and operations.
- 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.
- A breakdown or breach of our information technology systems or data security could subject us to liability, cybersecurity risks, or interrupt the operation of our business.
- Failure to develop and maintain adequate financial controls could cause us to have material weaknesses, which could adversely affect our operations and financial position.
- We currently rely significantly on third parties to conduct our nonclinical testing and clinical studies and other aspects of our development programs.
- We do not have, and do not have plans to establish, manufacturing facilities.
- We currently have limited marketing capabilities and no sales organization.
- 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.

Risks Related to Drug Development and Commercialization

- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome.
- 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.
- We may experience difficulties in the enrollment of patients in our clinical trials, which may delay or prevent us from obtaining regulatory approval.
- Use of our proprietary patient-reported outcome measure, CeD PRO, in our CeDLara Phase 3 clinical trials of larazotide may adversely impact our ability to achieve a positive result from these clinical trials.
- There is significant uncertainty regarding the regulatory approval process for any investigational new drug, and substantial further testing and validation of our product candidates and related manufacturing processes may be required.
- 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.
- 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.
- 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.

- 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 and indications that may be more profitable.

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.
- 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 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.
- 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.
- 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.

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.
- Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval.
- Intense competition might render our gastroenterology products noncompetitive or obsolete.
- We might not receive all of the anticipated market exclusivity benefits of orphan drug designations.
- We face potential product liability exposures, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.

Risks Related to Our Common Stock

- The market price of our common stock has been and will likely in the future be volatile.
- Future sales and issuances of shares of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.
- If we fail to meet the requirements for continued listing on the Nasdaq Capital Market, our common stock could be delisted from trading, which could decrease the liquidity of our common stock and our ability to raise additional capital.
- Anti-takeover provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult.
- 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.
- We have not paid cash dividends in the past and do not expect to pay dividends in the future.

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PART I

Item 1. Business.

Overview

9 Meters is a clinical-stage company pioneering novel treatments for people with rare digestive diseases, gastrointestinal ("GI") conditions with unmet needs, and debilitating disorders in which the biology of the gut is a contributing factor. Our pipeline includes drug candidates for short bowel syndrome ("SBS"), celiac disease ("CeD"), multi-system inflammatory syndrome in children ("MIS-C") and a robust pipeline of early-stage candidates for undisclosed rare diseases and/or unmet needs.

In April 2020, we completed a merger (the "RDD Merger") with privately-held RDD Pharma, Ltd., an Israel corporation ("RDD") and subsequently changed our name from Innovate Biopharmaceuticals, Inc. to 9 Meters Biopharma, Inc. Shortly thereafter, we acquired Naia Rare Diseases, Inc. and completed the integration of all three entities during the year ended December 31, 2020.

Our current product development pipeline is described in the table below.

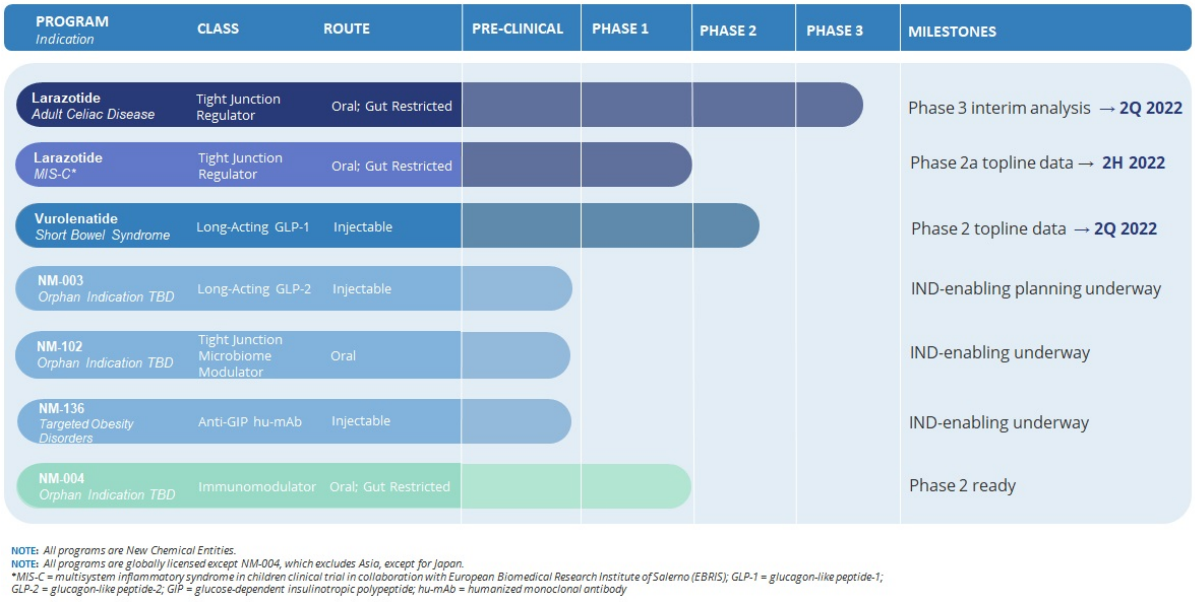


Figure 1: Current product development pipeline

Corporate Strategy

Our goal is to become a leading biopharmaceutical company focused on rare or debilitating digestive diseases that has the potential to transform current treatment paradigms for patients and address unmet medical needs. The critical components of our strategy are as follows:

- ***Advance the development of vurolenatide (NM-002) for the treatment of SBS.*** We completed the Phase 1b/2a clinical trial for the treatment of SBS. We announced positive topline results in December 2020, indicating that NM-002 met its primary objective, demonstrating excellent safety and tolerability. In addition, NM-002 demonstrated a clinically relevant improvement in total stool output ("TSO") volume within 48 hours of the first dose. We launched a multi-center, double-blind, double-dummy, placebo-controlled randomized Phase 2 trial in SBS in the second quarter of 2021, which, to our knowledge, is the largest placebo controlled Phase 2 trial in SBS. We expect topline results in the second quarter of 2022.
- ***Complete the Phase 3 clinical trial for larazotide (NM-001) for celiac disease.*** We initiated the Phase 3 trial for larazotide for treatment of celiac disease during 2019. We have three treatment groups, 0.25 mg of larazotide, 0.5

mg of larazotide and a placebo arm (total n=525) being conducted at over 100 clinical trial sites. Site activation and patient enrollment have been impacted by the COVID-19 pandemic. We continue to monitor the evolving situation with COVID-19, which could continue to directly or indirectly impact the pace of enrollment. The interim analysis is expected in June 2022.

- ***Advance our early-stage drug product candidates for undisclosed rare and unmet needs.*** We initiated IND-enabling activities for NM-102, our proprietary tight-junction microbiome regulator during 2021. NM-003, our long-acting GLP-2 agonist, is currently undergoing a preclinical proof-of-concept study. Also during 2021, we acquired a humanized monoclonal antibody targeting circulating glucose-dependent insulinotropic polypeptide (GIP), referred to as NM-136. We expect to progress at least one of these early-stage drug candidates to an IND in 2022.
- ***Acquire targeted clinical compounds for rare or debilitating digestive diseases with unmet needs***. We continually evaluate in-licensing opportunities and may acquire targeted clinical compounds for rare or debilitating digestive diseases. Focusing on rare or debilitating digestive diseases with unmet needs within GI allows for a targeted corporate development approach.
- ***Pursue a capital efficient commercialization strategy.*** For products with rare and/or orphan patient populations, our plan is to build an infrastructure to commercialize our drug products within the U.S. Drawing upon our expertise in both rare and digestive diseases, we aim to build a specialized yet efficient infrastructure that will support the entire commercialization continuum, including stakeholder education, treatment decision, and initiation and product access throughout the patient journey. In addition, we plan to seek partners to commercialize our drug products outside of the U.S. For large addressable markets, such as celiac disease, we plan to seek global partners with an established presence and history of successful commercialization.
- ***Leverage, protect and enhance our 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 our current product candidates for other indications and improve performance of existing product candidates. We plan to enhance the intellectual property portfolio further through learnings from ongoing clinical trials and manufacturing processes.
- ***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.

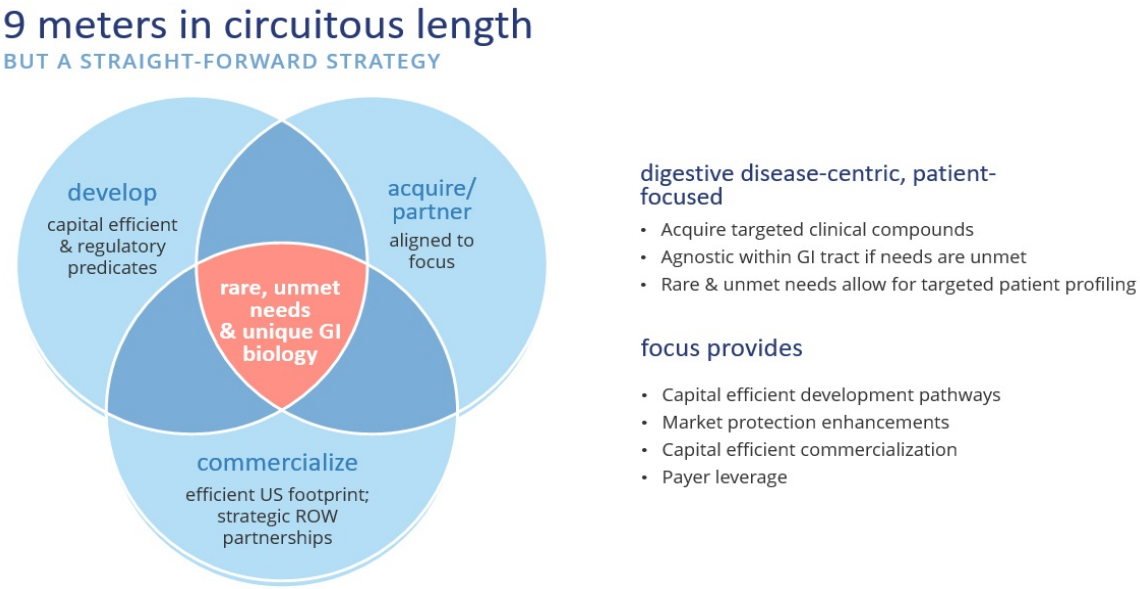


Figure 2: Corporate Strategy

Vurolenatide for the Treatment of Short Bowel Syndrome (SBS)

Short Bowel Syndrome Background

SBS is a debilitating orphan disease resulting from the physical or functional loss of the colon or small intestine. These functional and physical losses result from intestinal resection due to recurrent Crohn's disease, vascular events, trauma, malignancy, and complications from abdominal surgery. Such resections hinder absorption of water, vitamins, protein, fat, calories and other nutrients from food, resulting in diarrhea, dehydration and malnutrition. In addition, some patients have a life-long dependency on Parenteral Support ("PS"), which is the intravenous delivery of nutrition and fluids through a central line catheter. PS support is costly, burdensome, and associated with a myriad of complications. (Jeppesen 2014). A review of literature found that the mortality rate of adult patients with SBS ranges from 15-47% depending on age and length of parenteral nutrition (Schalamon 2003). Furthermore, a study that we commissioned found that SBS patients have a diminished quality of life due to urgent and frequent bowel movements at all times of the day, chronic diarrhea, weakness, exhaustion from dehydration, poor sleep quality, and mental anguish due to the impact of symptoms on their ability to live a normal life.

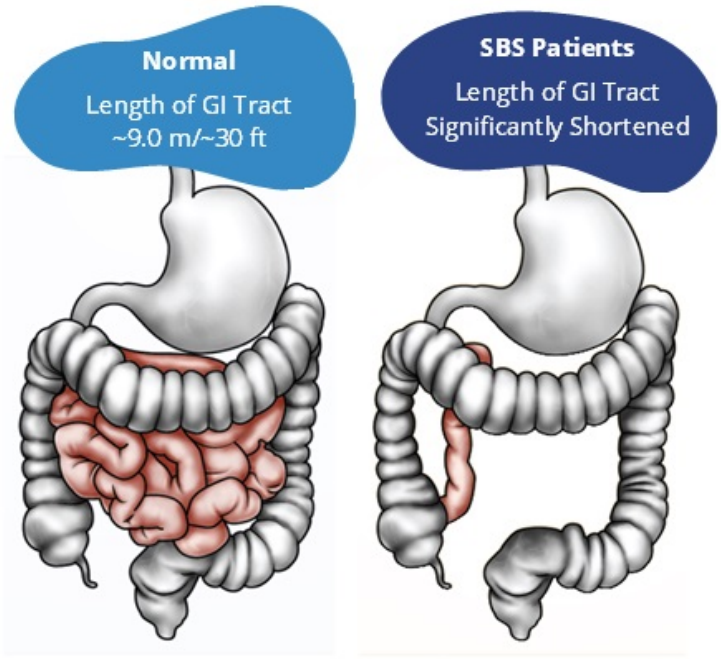


Figure 3: Short bowel syndrome disease profile

Teduglutide is a treatment that is approved for patients with SBS. Marketed as Gattex® in the United States and Revestive® in Europe, it is approved for the treatment of SBS patients 1 year and older who are dependent on PS. Teduglutide is an analog of glucagon-like peptide-2 (GLP-2), a hormone secreted postprandially by L-cells in sections of the bowel that are frequently removed in patients with SBS. GLP-2 is involved in regulating normal nutrient and energy absorption in the intestine. While teduglutide has demonstrated clinical benefits, it requires daily injections and a multi-step reconstitution process. In addition, teduglutide's patient population is constrained to patients who are dependent on PS and excludes PS patients with GI malignancies. Furthermore, a review of teduglutide US insurance claims across a 24-month period revealed a significant decline in persistency; 25% of patients discontinued therapy by month three, 38% discontinued by month six, 52% discontinued by month twelve and 66% by month twenty-four. (VectivBio Corporate Presentation).

Market Opportunity for SBS

The true incidence and prevalence of SBS are unknown because no reliable patient database exists. However, review of epidemiology from several sources indicates that there are an estimated 15,000 to 20,000 SBS patients in the United States and an additional 11,000 total patients in the EU4, United Kingdom and Canada. Furthermore, we believe that there is a significant patient opportunity in the Asia-Pacific region, the Middle East, and Latin America (Jeppesen 2013, Global Data, Charles River Associates).

Despite the limitations of teduglutide, Takeda reported global sales of 641 million U.S. Dollars in 2020. Takeda reported net sales of 492 million U.S. Dollars through the third quarter of 2021, which annualized is projected to be approximately 656 million U.S. Dollars. We believe that the SBS patient population utilizing teduglutide is a fraction of the total addressable SBS patient population. Accordingly, we believe that there is additional addressable global market opportunity for alternative therapeutic options that offer potential for improved dosing and administration, a faster onset of action, and an improved safety and tolerability profile.

Vurolenatide is 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. The long-acting linker technology is designed specifically to address the gastric effects in SBS patients by slowing digestive transit time. Vurolenatide uses proprietary XTEN® technology to extend the half-life of exenatide, allowing for potentially weekly to every other week dosing, which could increase convenience for patients and caregivers.

Vurolenatide 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, or the FDA. We completed our Phase 1b/2a study in adult patients suffering from SBS in December 2020, with the goal of demonstrating excellent safety and tolerability.

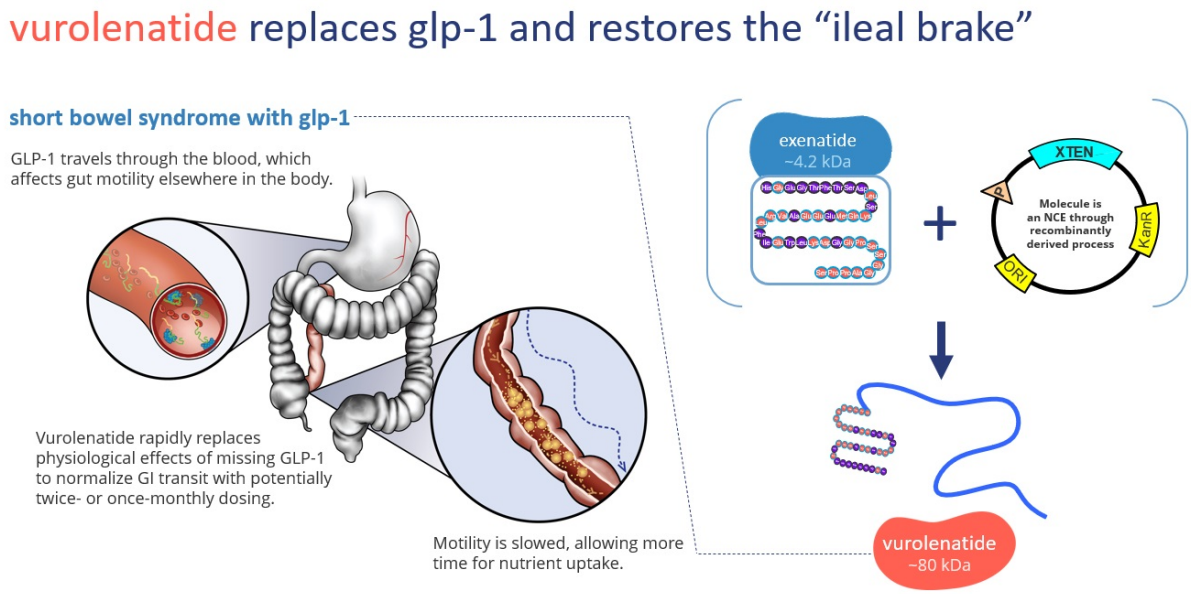


Figure 4: Vurolenatide Mechanism of Action

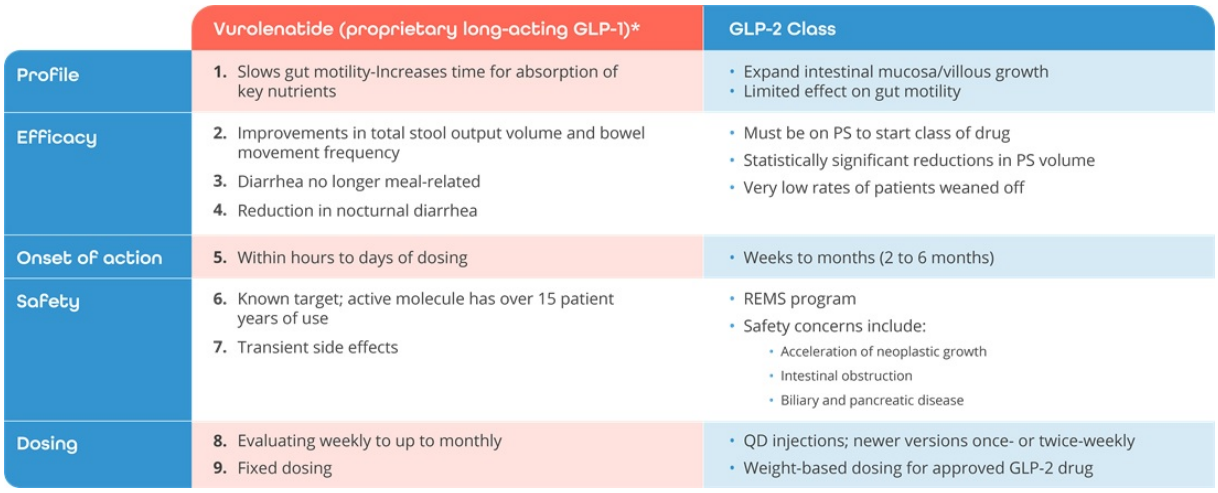


Figure 5: Potential Advantages of Vurolenatide

On December 7, 2020, we announced positive topline results from our ongoing Phase 1b/2a clinical trial for vurolenatide in SBS. The study met its primary objective as vurolenatide demonstrated excellent safety and tolerability. In addition, vurolenatide demonstrated a clinically relevant improvement in total stool output (TSO) volume within 48 hours of first dose.

The Phase 1b/2a clinical trial was an open-label, two-dose study evaluating the safety and tolerability of three escalating fixed doses of vurolenatide (50 mg, 100 mg, 150 mg) in nine adults with SBS for 56 days. The trial was conducted at Cedars-Sinai Medical Center. Patients in each of three cohorts received two subcutaneous doses two weeks apart with six weeks of subsequent follow-up. The study assessed the safety and tolerability of repeated doses on Days 1 and 15 at each dose level. Because reduced TSO volume and bowel movement frequency are correlated with improved intestinal absorption and potentially less need for intravenous supplementation for nutrition and hydration, these were key secondary objectives in the trial. The primary purpose of this open-label Phase 1b/2a study was to learn about the compound and its safety and potential efficacy to inform future development. The study protocol called for an analysis of urine output, however, it proved difficult to measure in an ambulatory setting and therefore the analysis is not expected to be meaningful.

Vurolenatide was generally safe and well tolerated: 17 treatment-emergent adverse events (TEAEs) were observed in nine patients, 15 of which were mild, transient and self-limited without further intervention. The majority of TEAEs were GI-related (nausea and vomiting).

Importantly, eight of the nine patients experienced meaningful declines in TSO following each dose, relative to a baseline output. The rapid onset of clinical improvements in stool volumes, as observed in all nine patients having substantial reductions in stool output within 48 hours of the first dose, shows the potential for vurolenatide to address the primary problem of chronic malabsorptive diarrhea in SBS patients. Additionally, four of seven patients showed reductions in bowel movement frequency after one dose and five of six evaluable patients showed reductions in bowel movement frequency after the second dose. Furthermore, of the five patients on parenteral support in the study, two patients showed reduction in PS after each dose. Results of the short form health survey quality of life instrument show directional improvement in multiple elements of health status over the course of the study. The short form health survey, or SF-36, is a set of generic, coherent and easily administered quality-of-life measures. These measures rely upon patient self-reporting and are now widely utilized by managed care organizations and by Medicare for routine monitoring and assessment of care outcomes in adult patients.

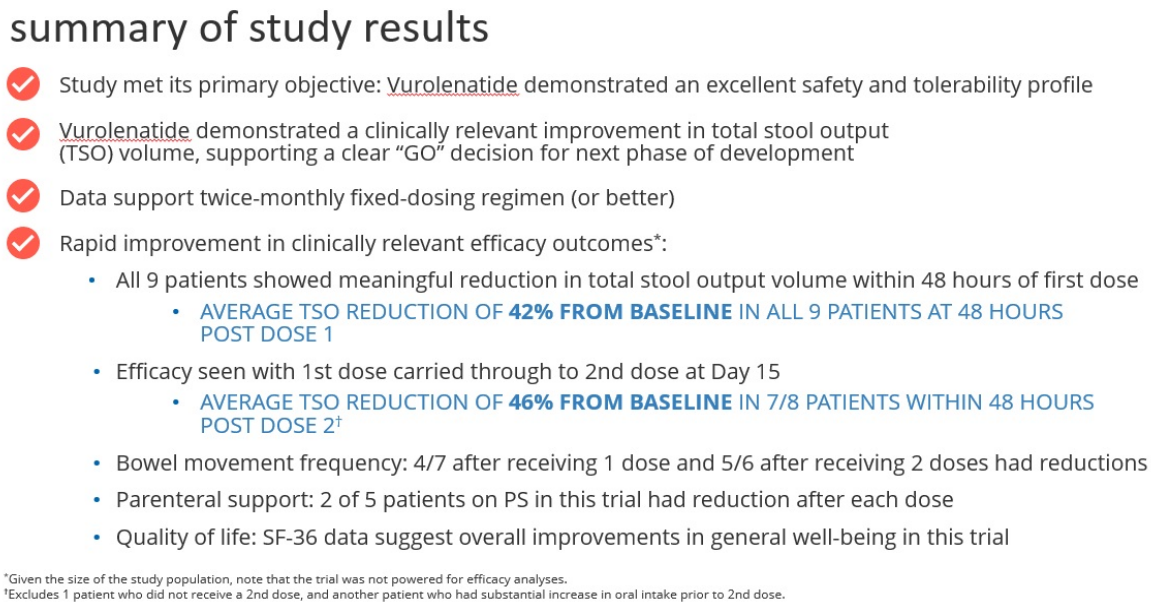


Figure 6: NM-002 Phase 1b/2a trial results

Following FDA communication in the first quarter of 2021, we initiated a Phase 2 study of vurolenatide for the treatment of SBS in the second quarter of 2021 with a target of recruiting approximately 22 patients using TSO as the primary efficacy outcome measure. This trial is a multi-center, double-blind, double-dummy, randomized, placebo-controlled trial. The FDA has provided global anchor questions and specific guidance for performance of exit interviews to support clinical meaningfulness of observed efficacy.

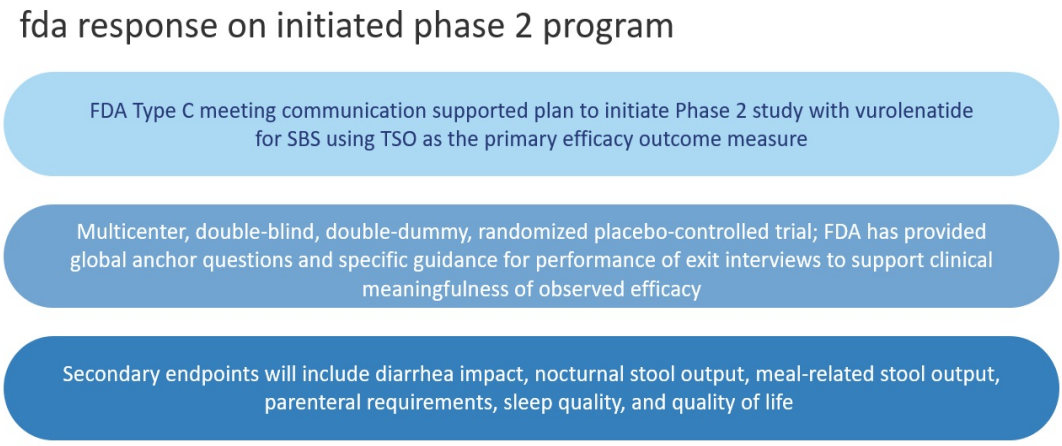


Figure 7: FDA Response on Planned Phase 2 program

We anticipate topline results from our Phase 2 study in the second quarter of 2022. Following Phase 2 results and an End-of-Phase 2 meeting, we plan to initiate a Phase 3 trial in the second half of 2022.

Larazotide for Celiac Disease (CeD)

Celiac Disease

CeD is a genetically linked, auto-immune mediated gastrointestinal disease that manifests as a life-long sensitivity to dietary gluten. Classical symptoms include abdominal pain, cramping, bloating, flatulence, diarrhea, and fatigue. Several in vitro and in vivo studies have demonstrated that permeability of the small intestine increases in CeD. This increased permeability potentiates the entrance of gliadin, a protein found in gluten, into the lamina propria, or mucosal membrane of the small intestine, through disassembly of the tight junction, a cell adhesion complex that regulates the leakage of solutes and water and seals the paracellular pathway of the small intestine. This cascade triggers an immune response and further disassembly of the tight junction (Khalegi 2016). CeD 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. Inadequately managed CeD can lead to complications including malnutrition, osteoporosis, neurologic conditions, lymphoma, and gastric cancers (Kurien 2016).

There is a strong genetic predisposition to CeD, with major risk associated with HLA DQ2 (approximately 95% of CeD patients) and HLA-DQ8 (approximately 5% of CeD patients) (Withoff 2016). In genetically predisposed individuals, the recognition of gliadin peptides by human leukocyte antigen (HLA) DQ2 and DQ8 T cells may be responsible for initiating the cascade of adaptive and innate autoimmune reactions responsible for mucosal destruction. The adaptive response is mediated by gluten-reactive CD4+ T cells in the *lamina propria* that recognize gluten-derived peptides. 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 CeD.

The current approach for diagnosis of CeD 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 CeD 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 CeD makes monitoring disease progression difficult. International guidelines have standardized definitions and criteria for the diagnosis of CeD, though there is less clear guidance for follow-up and monitoring. After initial diagnosis, the American College of Gastroenterology recommends annual follow-up performed by a healthcare provider with knowledge of CeD. Recommendations for monitoring disease progression may include assessing symptoms, dietary compliance, and repeating serology tests.

The global prevalence of CeD is estimated to be 1% of the population worldwide and growing, equating to approximately 3.2 million patients in the United States and approximately 3.5 million patients in the EU4, United Kingdom, and Northern Europe. The diagnostic journey is long and frustrating, with many patients waiting 6 to 10 years between the appearance of initial symptoms and diagnosis (beyondceliac.org). Furthermore, one study of U.S. claims found that patients with CeD incur greater healthcare costs versus controls (Capell).

Patients with CeD 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. 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 is 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, CeD patients have increased risks of exposure to gluten, which can cause symptoms more frequently. Multiple studies have shown that even those patients on a gluten-free diet suffer from symptoms, often consume gluten inadvertently, and have evidence of intestinal damage (Silvester 2020, Leffler 2015, Hall 2013).

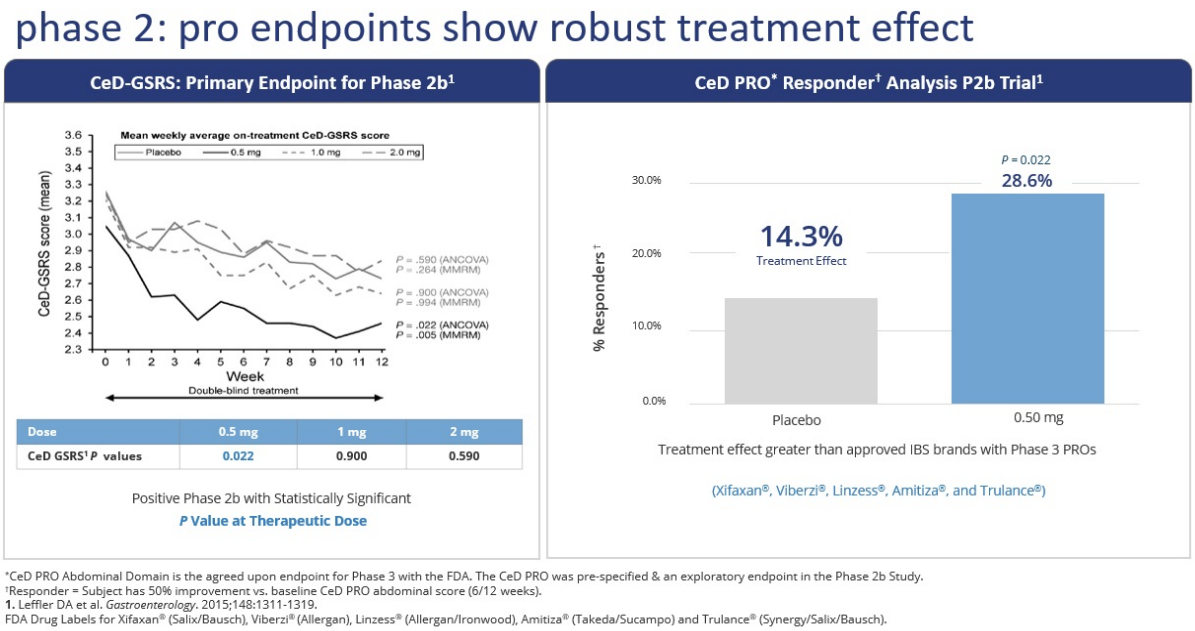
CeD patients are often categorized in three distinct groups: responsive to a gluten-free diet, non-responsive to a gluten-free diet, and refractory CeD. Non-responsive CeD is defined as continued symptoms, elevated serum antibodies, or villous

atrophy that persists despite following a gluten-free diet for six months or longer. Refractory CeD is defined as recurrent or persistent malabsorptive symptoms and villous atrophy despite strictly following a gluten-free diet for 12 months or longer. Non-responsive CeD is estimated to occur in 20-30% of CeD patients. Refractory CeD is estimated to occur in 1-2% of patients and is classified as a rare disease by the National Organization for Rare Diseases (NORD) (rarediseases.org). A study that we commissioned found that CeD patients suffer both physical and emotional pain, with constant bloating, diarrhea, and fatigue and persistent anxiety stemming from a fear of gluten cross-contamination.

Larazotide

Larazotide is being developed for the treatment of CeD and has successfully completed a Phase 2b trial showing statistically significant reduction in abdominal and non-GI (headache) symptoms. Larazotide is an 8-amino acid peptide formulated into an orally administered capsule and has been tested in nearly 600 CeD patients with statistically significant improvement in CeD symptoms. The FDA has granted larazotide Fast Track Designation for CeD. Larazotide's safety profile has been similar to placebo. In addition, the FDA granted a thorough QT (TQT) study waiver. The waiver supports larazotide's strong precedent of safety and could potentially streamline the program's timeline and cost effectiveness. Additionally, larazotide's mechanism of action as a tight junction regulator is a new approach to treating autoimmune diseases, such as CeD. 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.

With the release of the Phase 2b trial data in 342 CeD patients at the 2014 Digestive Disease Week conference, larazotide became the first and the only drug for the treatment of CeD (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 CeD created specifically for CeD and wholly owned by us ("CeD PRO"). We completed the End-of-Phase 2 meeting with the FDA, which confirmed the regulatory path forward and we launched the Phase 3 registration program in 2019.



*CeD PRO Abdominal Domain is the agreed upon endpoint for Phase 3 with the FDA. The CeD PRO was pre-specified & an exploratory endpoint in the Phase 2b Study.
†Responder = Subject has 50% improvement vs. baseline CeD PRO abdominal score (6/12 weeks).
1. Leffler DA et al. *Gastroenterology*. 2015;148:1311-1319.
FDA Drug Labels for Xifaxan® (Salix/Bausch), Viberzi® (Allergan), Linzess® (Allergan/Ironwood), Amitiza® (Takeda/Sucampo) and Trulance® (Synergy/Salix/Bausch).

Figure 8: 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. Source: Gastroenterology 2015; 148:1311–1319; p. 1315

Larazotide is an orally administered, locally acting, non-systemic, synthetic 8-amino acid, tight junction regulator being investigated as an adjunct to a gluten-free diet in CeD 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.

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 CeD mouse model (Gopalakrishnan, 2012). In doing so, it is proposed that larazotide reduces the symptoms associated with CeD. 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 CeD.

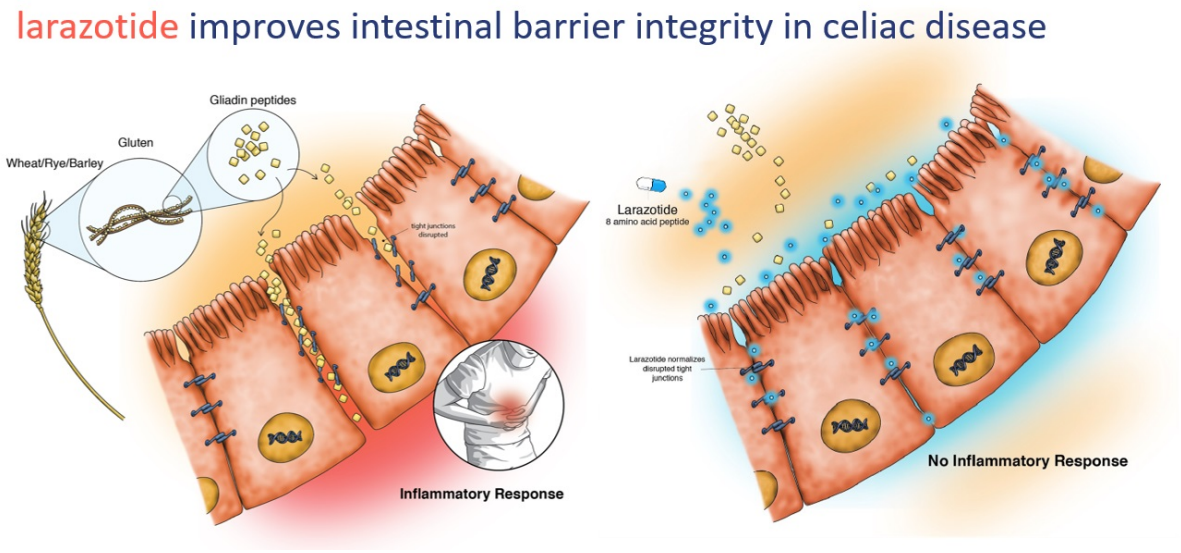


Figure 9: Larazotide intestinal barrier response

Larazotide's Dose Response

In several clinical trials, larazotide has exhibited clinical benefit by reducing CeD symptoms at lower doses while inhibition of this activity occurs at the higher doses. To better understand this observation, the pharmacology of larazotide was evaluated in an *ex vivo* porcine model. The study revealed that a specific aminopeptidase located within the brush borders of the intestinal epithelium cleaves larazotide into two fragments. These cleaved fragments 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 production of breakdown fragments, which then compete with and block activity of larazotide after a threshold concentration is reached. These data also provide the scientific basis for the observation of clinical efficacy at a lower dose of larazotide (i.e., a dose when competing inactive fragments are absent or at a low concentration).

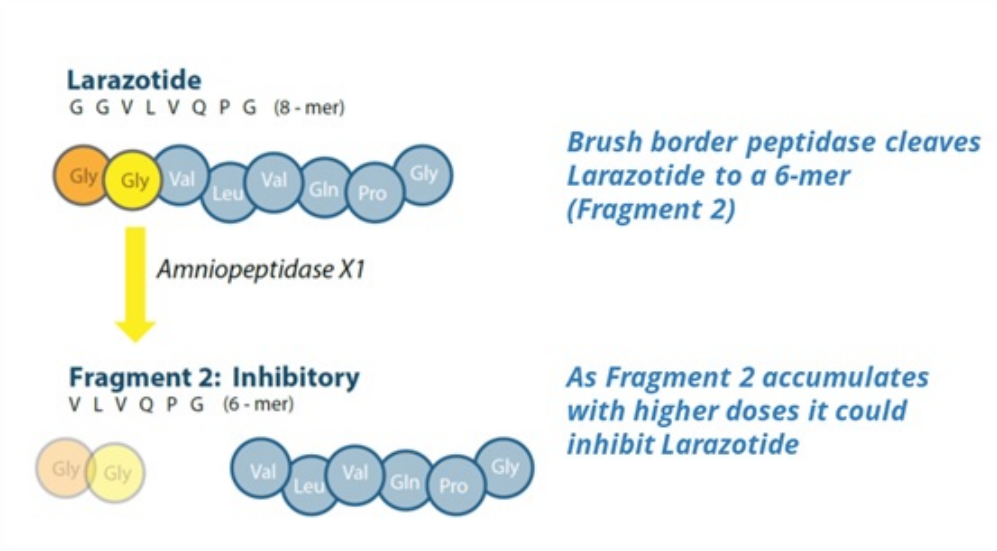


Figure 10: An aminopeptidase in the brush border cleaves larazotide into two fragments: fragment 2 acts as an inhibitor of larazotide

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 participants and a Phase 1b proof of concept trial in participants with CeD, and two Phase 2 gluten challenge studies in participants with controlled CeD. Additionally, larazotide was tested in two Phase 2 trials in participants with active CeD (Figure 11). After exposure in more than 600 participants, 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 CeD was filed with the FDA by Alba Therapeutics Corporation ("Alba") on 12 August 2005 for the use of larazotide acetate (NM-001). The IND was transferred from Alba to Innovate effective March 8, 2016. During 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 Participants
-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

Figure 11: Significant drug exposure in the participants 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 participants with well-controlled CeD on a gluten-free diet. Participants 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). Participants remained on their gluten-free diets throughout the duration of the trial except for 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 participants with CeD undergoing a gluten challenge.

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

The purpose of the -012 study was to assess the efficacy (reduction and relief of signs and symptoms of CeD) of 3 different doses of larazotide (0.5 mg, 1 mg and 2 mg TID) versus placebo for the treatment of CeD 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.

The CeD PRO showed a 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 drugs approved for irritable bowel syndrome (“IBS”) and chronic idiopathic constipation (“CIC”) which use a similar clinical trial design.

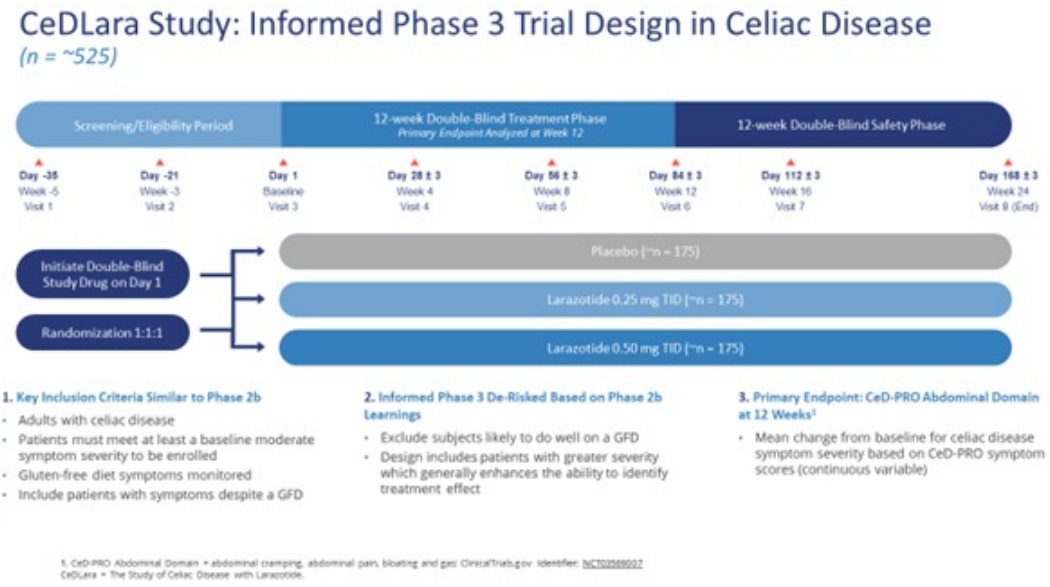


Figure 12: Phase 3 trial design for the treatment of celiac disease

The Phase 3 trial is a randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of larazotide acetate for the relief of persistent symptoms in patients with CeD on a gluten-free diet. The trial consists of a screening/eligibility period, a 12-week double-blind treatment phase and a 12-week double-blind safety phase. The primary outcome measure is the change from baseline to the 12-week double-blind treatment phase in CeD-PRO Abdominal Domain scores. Key inclusion criteria include adult patients diagnosed with CeD (positive celiac serology plus consistent biopsy histology) for at least 6 months, on a gluten-free diet for at least 6 months, experiencing symptoms (i.e., abdominal pain, abdominal cramping, bloating, gas, diarrhea, loose stools or nausea), and those willing to maintain current gluten-free diet throughout the participation of the study. Patients screened with refractory celiac or severe complications of celiac disease and/or chronic active GI disease other than CeD are excluded from the study.

Larazotide CeD Target Product Profile	
Indication	• Relief of persistent symptoms in patients with celiac disease on a GFD
Therapeutic Modality	• Gut-restricted tight-junction regulator
Dosing Regimen	• 3 times daily, 15 minutes before each meal
Dosage Form / Delivery Mode	• Oral capsule, gut-restricted, not absorbed
Population	• Adult celiac patients, non-responsive to GFD
Efficacy	• Significant reduction in symptoms as measured by the CeD-PRO (Celiac Disease Patient Reported Outcome) abdominal domain scale (measures changes in abdominal pain, abdominal bloating, abdominal cramps and flatulence)
Safety	• Strong safety profile compiled by dosing 600+ patients to date • In Phase 2b, most common gastrointestinal AEs were diarrhea (8.2%), nausea (4.7%), constipation (3.5%) • Larazotide's excellent safety and tolerability profile was similar across all dose levels
Cost of Goods	• Drug product can be manufactured at scale at costs in line with other peptide therapeutics
Sales Call Point	• GI specialist, primary care physician
Market Exclusivity	• Broad worldwide protection through 2035 with patent line extension

Figure 13: Larazotide Target Product Profile

We have over 100 active clinical trial sites in our Phase 3 trial 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 COVID-19 pandemic. 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. In addition, after consultation with the FDA, the analytical approach to the primary endpoint was modified to perform a continuous variable analysis instead of a responder analysis of the primary efficacy outcome. The revised methodology enabled a more capital-efficient study, with reduction in participants from 630 to 525. We expect the interim analysis in June of 2022. The interim analysis will perform a sample size re-estimation that will preserve statistical alpha. During 2021, we engaged Beyond Celiac and The Celiac Disease Foundation to further identify potential and appropriate patients for enrollment in the Phase 3 trial. Additionally, we implemented multiple social media initiatives to potentially enhance enrollment.

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 larazotide is approved by the FDA and is the first drug to be approved for CeD, we believe that the PRO will become the standard for assessing efficacy in CeD. 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.

Expanded Access Program

In January 2021, we instituted an Expanded Access Program for Larazotide. Expanded access, sometimes called "compassionate use," is the use of investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment

options. The rules and regulations related to expanded access are intended to improve access to investigational drugs for patients who may benefit from investigational therapies. Expanded access studies conducted under this program are uncontrolled, carried out by individual investigators and not typically conducted in strict compliance with cGCPs, all of which can lead to a treatment effect which may differ from that in placebo-controlled trials. These studies provide only anecdotal evidence of efficacy for regulatory review. These studies contain no control or comparator group for reference and these patient data are not designed to be aggregated or reported as study results. Moreover, data from such small numbers of patients may be highly variable. Information obtained from our Expanded Access Program may not reliably predict the efficacy of our product candidates in company-sponsored clinical trials and may lead to adverse events that could limit our ability to obtain regulatory approval with labeling that we consider desirable, or at all.

Larazotide for the Treatment of Multi-system Inflammatory Syndrome (MIS-C)

We entered into a collaboration with the European Biomedical Research Institute of Salerno, Italy (EBRIS) to study larazotide for the treatment of MIS-C. MIS-C is a rare and serious complication of COVID-19 with symptoms that resemble those of Kawasaki disease, potentially including persistent fever, gastrointestinal symptoms, myocardial dysfunction, and cardiogenic shock with ventricular dysfunction in the setting of multisystem inflammation. MIS-C occurs when SARS-CoV-2 superantigens move through the tight junctions between the gut epithelial cells into the bloodstream, leading to the hyperinflammatory immune response. We believe that larazotide's mechanism of action as a tight junction regulator may prevent SARS-CoV-2 superantigens from entering the bloodstream. Following receipt of a Study May Proceed letter from the FDA under a recently filed Investigator IND, EBRIS initiated a Phase 2a study in MIS-C in the fourth quarter of 2021 to evaluate the use of larazotide in a group of children through a randomized placebo-controlled trial at MassGeneral Hospital for Children led by pediatric pulmonologist Lael Yonker, M.D. Under the terms of the collaboration agreement, we will supply larazotide for the purposes of the clinical study and EBRIS will be responsible for conducting the Phase 2a trial inclusive of all associated clinical costs.

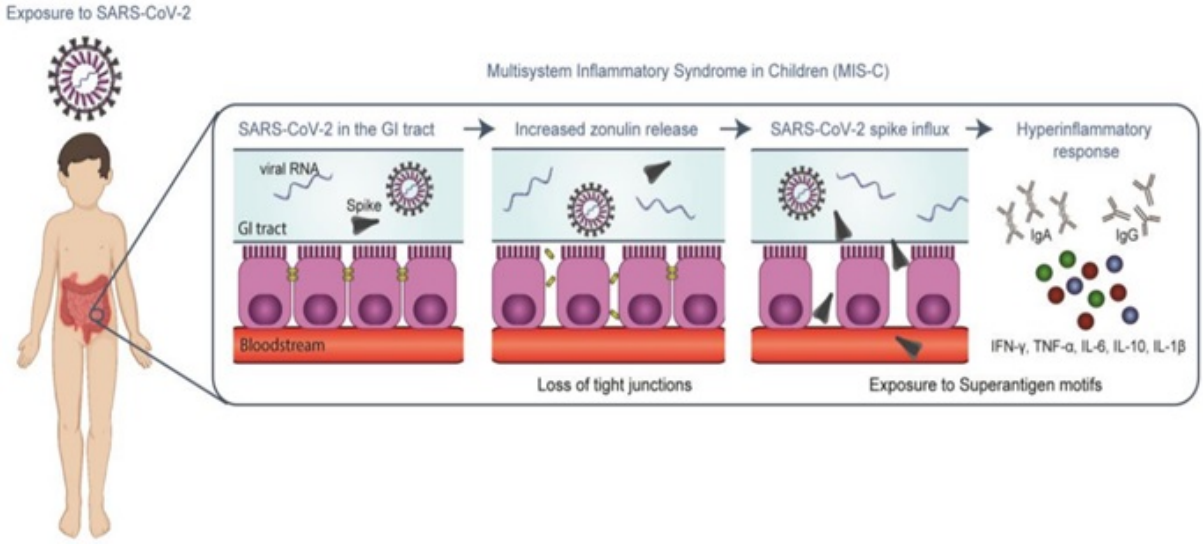


Figure 14: Multisystem Inflammatory Syndrome in Children (MIS-C)

Product Candidates being Evaluated for Development in Rare or Debilitating Digestive Diseases with Unmet Needs

NM-102, a small molecule peptide, is being developed as a potential microbiome modulator and is undergoing an indication selection process. NM-102 is a long-acting, degradation-resistant peptide, believed to be gut-restricted, and presumed to prevent antigens from trafficking into systemic circulation. Researchers found that NM-102 was effective alone or when combined with immune checkpoint inhibitors (ICIs) in a pre-clinical transgenic mouse model of spontaneous aggressive skin melanoma. Furthermore, the combination of NM-102 with ICIs improved survival compared to ICIs alone. We are currently progressing NM-102 through IND-enabling studies. On November 10, 2021, we entered into a collaboration with Gustave Roussy to investigate how tumors in preclinical models may affect intestinal integrity and in turn compromise the fitness of the host's immune system and its capacity to respond to ICIs. Further work is planned to decipher the

mechanism of NM-102 and its effects on intervening on the epithelial layer of the GI tract, as well as its potential translation to ICI efficacy in preclinical cancer *in vivo* models. Furthermore, on March 2, 2022, we announced a collaboration with NYU Langone Health investigating the pre-clinical use of NM-102 for an undisclosed autoimmune condition with a large unmet need.

NM-003 is a proprietary long-acting GLP-2 agonist with improved serum half-life compared with short-acting versions, which we intend to progress through a clinical and regulatory pathway in an undisclosed orphan and rare GI indication. On December 9, 2020, we announced that the FDA has granted orphan drug designation to NM-003, a proprietary long-acting GLP-2 receptor agonist, for prevention of acute graft versus host disease. NM-003, also called teduglutide, is designed as a long-acting injectable GLP-2 receptor agonist that utilizes proprietary XTEN® technology to extend circulating half-life. NM-003 is currently undergoing an indication selection process through an ongoing probability of technical and regulatory success analysis.

NM-136 targets glucose-dependent insulinotropic polypeptide (GIP), a hormone found in the upper small intestine that is released into circulation after food is ingested, and when found in high concentrations, can contribute to obesity and obesity-related disorders. NM-136 has been shown to prevent GIP from binding to its receptor, which in a preclinical obesity model showed a significant decrease in weight and abdominal fat by reducing nutrient absorption from the intestine as well as nutrient storage without affecting appetite. We are continuing the manufacturing and IND-enabling studies of NM-136 and intend to initiate a clinical proof-of-concept study in 2023.

NM-004 is a double-cleaved mesalamine with an immunomodulator. NM-004 is also undergoing a portfolio rationalization and indication selection process. NM-004 is patent-protected and has orphan designation for pediatric ulcerative colitis.

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.” We also rely on trade secrets that may be important to the development of our business.

In addition to patents and applications that we have licensed, we are the owner or co-owner of patent applications that have been filed relating to potential expansion of our product pipeline. We are the owner or co-owner of 2 issued or allowed U.S. patents and 2 issued or allowed foreign patents, as well as 32 pending patent applications covering formulations of larazotide and related compounds and methods of use for larazotide and related compounds (including NM-102). Some of these applications are co-owned with North Carolina State University, University of Maryland, Baltimore, or Oklahoma Medical Research Foundation. In addition, we are the owner of two pending patent applications relating to uses and formulations of APAZA (NM-004) and related molecules. We are also the owner of a pending patent application covering methods of use of GLP-1 receptor agonists, including vurolenatide. The patents and patent applications that we own or co-own provide patent terms or anticipated patent terms ranging from 2038 to 2043.

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.”

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 CeD. We now refer to this program as larazotide or NM-001. 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) two patent families that are jointly owned by Alba and UMB. 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 larazotide in excess of $1.5 billion. Upon the first commercial sale of larazotide, 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. The patents subject to the Alba sublicense have since expired. 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 patents covering the composition-of-matter for the larazotide peptide are recently expired. The Alba Therapeutics patent estate nevertheless includes issued patents that provide product exclusivity for larazotide in the U.S. until June 4, 2031, not including patent term extensions that may apply upon product approval. Outside the U.S., the Alba Therapeutics patent estate includes issued patents that provide product exclusivity for larazotide until February 9, 2027, not including patent term extensions, such as Supplementary Protection Certificate, that may apply in various jurisdictions.

Significant patents in the larazotide patent estate include issued patents in the U.S. for methods of treating CeD with larazotide, (US Patents 8,034,776 and 9,279,807), of which the last to expire has a term to July 16, 2030.

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 larazotide patent estate formulation patent family includes patents covering the drug product composition-of-matter (US Patent 9,265,811) and corresponding methods of treatment (U.S. 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, and which may be the subject of Patent Term Extension upon approval.

The Alba Therapeutics patent estate further includes one patent family relating to the clinical dose and use for larazotide, and which is pending in the U.S., Europe, Canada, China and Hong Kong. If issued, this patent would provide exclusivity for the larazotide program through April 3, 2035, not including patent term extensions that may apply. The Alba Therapeutics patent estate also includes one issued U.S. patent covering the NM-102 program through May 6, 2029.

License with Seachaid Pharmaceuticals, Inc.

In April 2013, we entered into a sub-license agreement (the "Seachaid License") with Seachaid Pharmaceuticals, Inc. ("Seachaid") to further develop and commercialize the licensed product, known as APAZA, or NM-004. Seachaid controlled rights to these patents by a license from Biocon Ltd.

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, use, or manufacture of any NM-004 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 or (ii) the date that one or more generic equivalents of 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 Seachaid patent estate includes issued patents for:

i. methods and compositions employing 4-aminophenylacetic acid, of which the last to expire has a term to March 22, 2025 (in the U.S. and Europe); and

ii. 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).

License Agreement with Amunix

In connection with the Naia Acquisition, we entered into two amended and restated license agreements with Amunix Pharmaceuticals, Inc. (“Amunix”), pursuant to which we received an exclusive, worldwide, royalty-bearing license, with rights of sublicense, to lead molecules exenatide (a GLP-1 receptor agonist) and GLP-2 analog fused to an XTEN amino acids sequence and other intellectual property referenced therein (the “Amunix Licenses”). Also in connection with the Naia Acquisition, we entered into an amended and restated license agreement with Cedars-Sinai Medical Center (“Cedars”), pursuant to which we licensed the rights to GLP-1 receptor agonist for the treatment of SBS (the “Cedars License” and together with the Amunix Licenses, the “Naia Licenses”). Collectively, the Naia Licenses are intended to support our development of a therapy to treat SBS, which we refer to as NM-002.

Naia paid initial license fees and other development milestone payments due under the Naia Licenses prior to the Naia Acquisition, therefore, we did not pay any initial license fees upon the amendment and restatement of the original Naia Licenses. Pursuant to the terms of the Amunix Licenses, we agreed to expend in certain minimum financial amounts in direct support of development of the GLP-1 and GLP-2 products during specified development stages.

As consideration under the Amunix License for the GLP-1 receptor agonist rights, we agreed to pay Amunix certain royalty payments and (i) $70.4 million in milestone payments upon achievement of future development and sales milestones in the U.S. and major EU countries, (ii) $20.5 million in milestone payments upon achievement of future development and sales milestones in China and certain related territories, and (iii) $20.5 million in milestone payments upon achievement of future development and sales milestones in South Korea and certain other East Asian countries. As consideration under the Amunix License for GLP-2 rights, we agreed to pay Amunix certain royalty payments and $60.1 million in milestone payments upon achievement of future development and sales milestones in the U.S. and major EU countries.

As consideration under the Cedars License, we agreed to pay Cedars certain royalty payments and approximately $9.4 million in milestone payments upon achievement of future development and sales milestones.

The majority of the intellectual property licensed from Amunix is controlled and maintained by Amunix and relates to their proprietary XTEN fusion protein technology, including fusion protein compositions, methods of use, and methods of manufacturing.

License Agreement with MHS Care Innovation LLC

During July 2021, we entered into an amended and restated technology license agreement with MHS Care-Innovation LLC ("MHS"), pursuant to which we received an exclusive, worldwide license, with rights to sublicense, to certain patent and other intellectual property rights concerning a proprietary and highly specific humanized monoclonal antibody that targets glucose-dependent insulinotropic polypeptide (the "MHS License"). The MHS License does not require the payment of any future milestone payments or royalties to MHS, since it was originally entered into with Lobesity in exchange for the issuance of certain equity securities and a grant of certain related rights to Lobesity, all of which occurred prior to the execution of the MHS License. As consideration for the assets purchased in the Lobesity Acquisition (including but not limited to the MHS License), we are obligated to pay Lobesity (i) potential worldwide regulatory and clinical milestone payments totaling $45.5 million for a single indication (with the total amount payable, if multiple indication are developed, not to exceed $58.0 million), (ii) up to $50.0 million in global sales-related milestone payments, and (iii) subject to certain adjustments, a mid-single digit royalty on worldwide net sales.

License Agreement with EBRIS

On August 6, 2021, we announced a collaboration with EBRIS to study larazotide for the treatment of MIS-C. In connection with this collaboration, the Company paid a milestone fee of $0.5 million upon IND approval for MIS-C.

Manufacturing and Supply

We contract with third parties for the manufacturing of all of our product candidates, and 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 and 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 demand 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.

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 safe and effective product candidates that address the unmet needs of patients.

The competitive landscape in SBS is currently limited, which we believe is due to the previous regulatory precedent set by the approved agent teduglutide. To our knowledge, there are two therapies (glepaglutide and apraglutide) currently in Phase 3 trials, both of which are GLP-2 agonists, as well as a dual GLP-1/GLP-2 agonist (dapiglutide), and a dual GLP-1/glucagon agonist (efinopegdutide) in Phase 1. To our knowledge, there is no single agent approach dedicated to studying SBS patients using a GLP-1 agonist approach other than vurolenatide. A summary of the drugs in development for SBS is below:

Class	MOA Description	Agents in Development	Phase	Route of Administration
GLP-2 analogs	Expands intestinal mucosa and villous growth to increase intestinal absorption	HM15912 – Hanmi Pharma	Phase 2	Subcutaneous
		Glepaglutide – Zealand Pharma	Phase 3	Subcutaneous
		Apraglutide – Vectiv Bio	Phase 3	Subcutaneous
Dual GLP-1 + Other Agonists	Combines GLP-2 analog with GLP-1	Dapilgutide – Zealand Pharma	Phase 1	Subcutaneous
	Activates GLP-1 and glucagon receptors	HM12525A – Hanmi/Merck	Phase 2	Subcutaneous
Enteric-Coated Cholestyramine	Binds to bile acids after fat ingestion but before diarrhea formation in the colon	ECC Capsules – PharmaScience	Phase 2 (recently terminated)	Oral

The competitive landscape in CeD has been limited historically, 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 CeD, and given the unmet medical needs in these areas, we anticipate increasing competition. We are aware of 12 different products in Phase 1 or 2 development. These products are classified within 6 classes, as follows: gluten protein degradation agents, monoclonal antibodies, immune tolerance induces, integrin inhibitors, TG2 inhibitors, and recombinant bovine IAP. A summary of the drugs in development for CeD is listed below:

Class	MOA Description	Agents in Development	Phase	Route of Administration
Gluten protein degradation agents	Degrades gluten to ameliorate/eliminate immune reaction	TAK-062 – Takeda	Phase 1	Oral
		Latiglutenase – Immunogenx, Alvine	Phase 2	Oral
Monoclonal Antibodies	Blocks IL-15 to inhibit immune system function	CALY-002 – Calypso Biotech	Phase 1	IV
		Hu-Mik Beta 1 – Mayo clinic	Phase 1	Subcutaneous
		BNZ-2 – Bioniz Therapeutics	Phase 1	Subcutaneous
		AMG-714/PRV-015 Amgen/ Provention Bio	Phase 2	Subcutaneous
Immune tolerance inducers	Reprograms immune cells not to respond to gluten antigens	KAN-101 – Anokion, Kanyos Bio	Phase 1	IV
		AG017 – ActoBio	Phase 1 (End of Pre-Clinical)	Subcutaneous
		TAK-101 – Takeda/Cour Pharma	Phase 2	IV
Recombinant bovine IAP	Diminishes intestinal inflammation, tightens gut barrier and promotes microbiome health	SYN-020 – Synthetic Biologics	Phase 1	Oral
Integrin inhibitor	Immune trafficking, blocking immune cells from traveling from blood to the intestines	PTG-100 – Stanford University	Phase 1	Oral
TG2 inhibitors	Targets the dysregulated TG2 within the small intestine, to prevent the immune response to transglutaminase-modified gluten	GSK3915393 – GlaxoSmithKline	Phase 1	Oral
		ZED 1227 – Zedira / Dr. Falk	Phase 2	Oral

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

Before any of our drug product candidates may be marketed in the United States, they must be approved by the FDA. 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 ("GLP") regulations;
- submission to the FDA of an Investigational New Drug application, or IND, which must become effective before human 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 required by the FDA;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practices, or cGMP, and to assure that the facilities, methods, and controls are adequate to preserve the product's continued safety, purity and potency, and of selected clinical investigational sites to assess compliance with current Good Clinical Practices, or cGCPs; and
- FDA review and approval of the NDA to permit commercial marketing of the product for particular indications for use in the United States, which must be updated annually and when significant changes are made.

The testing and approval processes require substantial time, effort, and financial resources and 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 product candidates. The FDA may delay or refuse approval of an NDA if applicable regulatory criteria are not satisfied, or may require additional testing, information and/or post-marketing testing and surveillance to monitor safety or efficacy of a product candidate.

If regulatory approval of a product candidate 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 ("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 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 product candidates under development.

Expedited Development and Review Programs

A sponsor may seek approval of a product candidate under programs designed to accelerate the FDA's review and approval of new drug candidates that meet certain criteria. Specifically, a new drug candidate is eligible for Fast Track designation if it is intended to treat a serious or life-threatening condition, fill an unmet medical need, and demonstrate a significant improvement in the safety or effectiveness in the treatment of that condition. The FDA has granted larazotide Fast Track designation for CeD.

A drug that receives Fast Track designation is eligible for the following:

- more frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval;
- more frequent written correspondence from FDA about the design of clinical trials;
- priority review to shorten the FDA review process for a new drug from ten months to six months; and,
- rolling review, which means 9 Meters can submit completed sections of its NDA for review by FDA, rather than waiting until every section of the application is completed before the entire application can be reviewed.

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.

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. 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.

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 product candidate;
- 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.

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

NM-002 has received orphan drug designation by the FDA. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug candidate 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 the 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.

Orphan drug exclusivity may be lost if the FDA or the European Medicines Agency ("EMA") determines that the request for designation was materially defective, or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition or if the incidence and prevalence of patients who are eligible to receive the drug in these markets materially increase. The inability to obtain or failure to maintain adequate product exclusivity for our product candidates could have a material adverse effect on our business prospects, results of operations and financial condition.

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 the FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services ("CMS"), the U.S. Department of Health and Human Services ("DHHS") Office of Inspector General ("OIG") and other division of DHHS, 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, the Physician Self-Referral law (the "Stark Law"), physician payment transparency laws, privacy laws, security laws, anti-bribery and anti-corruption laws, and other federal and state laws similar to the foregoing.

Our business and our relationships with customers, physicians, and third-party payors are and will continue to be subject, directly and indirectly, to federal and state health care fraud and abuse laws and regulations. These laws also apply to the physicians and third-party payors who will play a primary role in the recommendation and prescription of our product candidates, if they become commercially available products. These laws may constrain the business or financial arrangements and relationships through which we might market, sell and distribute our products and will impact, among other things, any proposed sales, marketing and educational programs. There are also laws, regulations and requirements applicable to the award and performance of federal grants and contracts.

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 reimbursement of overpayments, 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 earnings—any of which could adversely affect our ability to operate our business and our financial results.

Restrictions under applicable federal and state healthcare related laws and regulations include but are not limited to the following:

- the federal Anti-Kickback Statute, which prohibits persons from, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, the referral of an individual for the furnishing or arranging for the furnishing, or the purchase, lease or order, or arranging for or recommending purchase, lease or order, of any good or service for which payment may be made under a federal healthcare program;
- the civil federal False Claims Act, which imposes civil penalties, including through civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent; knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; conspiring to defraud the government by getting a false or fraudulent claim paid or approved by the government; or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the criminal federal False Claims Act, which imposes criminal fines or imprisonment against individuals or entities who willfully make or present a claim to the government knowing such claim to be false, fictitious, or fraudulent;
- the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations (collectively, "HIPAA"), which imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as directly applicable privacy and security standards and requirements; HIPAA also imposes criminal liability for, among other actions, knowingly and willfully executing a scheme to defraud any healthcare benefit program, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense, or knowingly and willfully making false statements relating to healthcare matters;
- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- federal transparency laws, including the federal Physician Sunshine Act (PSA) created under Section 6002 of the Affordable Care Act and its implementing regulations. The PSA requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare and Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians (as defined above) and their immediate family members; and
- analogous or similar state, federal, and foreign laws, regulations, and requirements—such as state anti-kickback and false claims laws—which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; laws, regulations, and requirements applicable to the award and performance of federal contracts and grants and state, federal and foreign laws that govern the privacy and security of health and other information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other laws, regulations, or other requirements that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, restitution exclusion from government funded healthcare programs, corporate integrity agreements, deferred prosecution agreements, debarment from government contracts and grants and refusal of future orders under existing contracts, contractual damages, the curtailment or restructuring of our operations and other consequences. If any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, that person or entity may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs. Moreover, availability of any federal grant funds which we may receive or for which we may apply is subject to federal appropriations law. Such grant funding may also be withdrawn or denied due to a violation of the above laws and/or for other reasons.

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 adopted an anti-corruption policy as a part of our Code of Business Conduct and Ethics in January 2021. 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 the 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 could have a negative impact on our business, on the results of our operations, and on our 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 product candidates. 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 product candidates 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 delivery and payment systems in ways that could materially affect our ability to sell our products, if approved, 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 to healthcare services. 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, the 2010 Patient Protection and Affordable Care Act (the “Affordable Care Act”) was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud

and abuse, promote quality improvement and evidence-based care, 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.

Efforts to reform the healthcare sector are ongoing. Since its enactment, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the Affordable Care Act. For example, the Tax Cuts and Jobs Act of 2017 ("TCJA") repealed the Affordable Care Act's "individual mandate." The repeal of this provision of the Affordable Care Act, which required most Americans to carry a minimal level of health insurance, became effective in 2019. It is unclear what impact the repeal of the individual mandate will have on the viability of the insurance marketplaces established under the Affordable Care Act or on the need for future reforms. The Trump administration also took executive actions to delay implementation of portions of the Affordable Care Act, including directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act's "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. Further, the Bipartisan Budget Act of 2018, among other things, amended the Affordable Care Act to increase the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." These revisions became effective January 1, 2019.

The Biden administration has signaled that it plans to build on the Affordable Care Act and to expand the number of people who are presently eligible for subsidies under the law. On January 28, 2021, President Biden issued a new Executive Order directing federal agencies to reconsider rules and other policies that limit Americans' access to health care and to consider actions that will protect and strengthen that access. Under this Executive Order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the Affordable Care Act that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the Affordable Care Act; and policies that reduce affordability of coverage or financial assistance, including for dependents.

The prices of prescription drugs have been the subject of considerable discussion and debate in the United States and abroad. There have been several recent U.S. congressional inquiries into prescription drug pricing, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for products. Any reduction in reimbursement from Medicare, Medicaid, or other government 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 and maintain profitability of our product candidates, if approved.

The Budget Control Act of 2011, for instance, created, among other things, measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction in funding to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2029 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020—and also extended the sequester by one year, through 2030. The American Taxpayer Relief Act of 2012 also reduced Medicare payments to certain providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws, and others, may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug formularies and other health care programs. These measures could reduce

the ultimate demand for our product candidates, if approved, and/or may constrain the prices that we are able to charge for such products. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

We expect further reform to the Affordable Care Act, to the Medicare and Medicaid programs, and to the regulation of the healthcare sector generally. Some of these changes could have a material adverse effect on our business and operations. Ongoing and future healthcare reform measures may result, for instance, in more rigorous coverage criteria and in additional downward pressure on the price that we receive for our product candidates, if approved, and could harm our future revenues. 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 product candidates to the extent we choose to develop or sell any product candidates 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.

Environmental, Social and Governance

The management team and Board of Directors of 9 Meters are keenly aware of the importance of environmental, social and governance issues, and the company's need to conduct business with high standards. Our mission as an organization is to be patient-centric and develop innovative treatments to liberate patients from rare and underserved diseases through our deep understanding of GI biology.

We collectively believe that pursuing an environmental, social and governance ("ESG") agenda serves the interests of all of our stakeholders, which includes our shareholders. Our employees, partners, and investors expect us to honor our values and take action to promote a more equitable and sustainable world for future generations.

As we further build our organization behind our pipeline of innovative products to treat rare and unmet needs in digestive diseases, we intend to strive to understand the perspectives of the diverse clients and communities we will serve, and as such, we are intensifying our efforts to drive diversity and inclusion and a culture of belonging throughout our organization. We will strive to comply with all applicable environmental laws, regulations and policies concerning environmental protection in all our business activities and in the selection of partners we choose to work with. We are committed to strengthening our local community by contributing through volunteerism and will continue, as we have been doing, to provide donations to parties we believe will support our goal in improving patient health and well-being. We are also committed to good corporate governance. All of our employees, officers and directors must conduct themselves according to the language and spirit of our Code of Conduct, and our Board of Directors is dedicated to providing effective corporate oversight including through oversight committees such as the Nominating and Governance Committee and the Audit Committee.

Human Capital

We currently have 21 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.

In response to the COVID-19 pandemic, we put in place several safety measures for our employees, patients, healthcare providers, and suppliers. These measures included, but were not limited to, substantially restricting travel, limiting access to our corporate office, including allowing employees to work remotely, providing personal protective equipment to employees, investigator sites and third-party vendors, implementing social distancing protocols, and coordinating safety protocols with our investigator sites.

Diversity, Equity and Inclusion

At 9 Meters, we are committed to diversity, equity and inclusion across all aspects of our organization, including hiring, promotion and development practices. We seek to build a diverse and inclusive workplace and have no tolerance for prejudice or racism. As of March 18, 2022, 38% of our employees were ethnically diverse individuals and 57% of our employees were female.

We are committed to ensuring our employees receive equal pay for equal work. We establish components and ranges of compensation based on market and benchmark data. Within this context, we strive to pay all employees equitably within a reasonable range, taking into consideration factors such as role, relevant experience, internal equity, job location, and individual, business unit and company performance. In addition, we are committed to providing benefits designed to allow our diverse workforce to have reward opportunities that meet their varied needs so that they are inspired to perform their best on behalf of patients and stockholders each day. We regularly review our compensation practices and analyze the equity of compensation decisions, for individual employees and our workforce as a whole. If we identify employees with pay gaps, we receive and take action to attain fidelity between our stated philosophy and actions.

Corporate Information

The Company 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 April 2020, the Company completed its merger with privately-held RDD Pharma, Ltd., an Israel corporation and changed its name from Innovate Biopharmaceuticals, Inc. to 9 Meters Biopharma, 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.9meters.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.

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

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 our current product development pipeline through regulatory approval and further develop future 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 acceptable 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, 2021 and 2020 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, 2021 and 2020 and had an accumulated deficit of $168.8 million as of December 31, 2021. 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 on a timely basis and on acceptable terms, if at all, 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, 2021 and 2020, we incurred losses from operations of $36.8 million and $61.5 million, respectively, and net cash used in operating activities was $29.5 million and $19.4 million, respectively. At December 31, 2021, we had an accumulated deficit of $168.8 million and cash and cash equivalents of $47.0 million. We expect to continue to incur substantial operating losses for the next several years as we advance our product candidates through clinical development, U.S. and other regional regulatory approvals and commercialization. No revenue from operations will likely be available until, and unless, one of our product candidates is approved by the FDA or another regulatory agency and successfully marketed, or we enter into an arrangement that provides for licensing revenue or other partnering-related funding, outcomes which we may not achieve on a timely basis or on acceptable terms, or at all.

Our capital requirements for the foreseeable future will depend in large part on our expenditures on our development programs. Future expenditures on our development programs are subject to many uncertainties 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 patients who participate, the rate of enrollment and the potential impact the COVID-19 pandemic could have on the expected timelines for each of our clinical programs;
- the number and size 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 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 and retaining qualified 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.

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.

Risks Related to Our Business Strategy and Operations

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 product candidates.

The success of our business is dependent on our ability to advance the clinical development of vurolenatide for the treatment of SBS, larazotide for the treatment of celiac disease and NM-136 for rare obesity disorders. We are also developing larazotide for the treatment of multisystem inflammatory syndrome in children (“MIS-C”) through a collaboration with EBRIS and NM-003, NM-102 and NM-004 for the treatment of undisclosed rare debilitating digestive diseases with unmet needs. We launched our Phase 2 VIBRANT clinical trial for vurolenatide in the second quarter of 2021 and we

currently anticipate topline data in the second quarter of 2022. In the third quarter of 2019, we started our Phase 3 CeDLara clinical trial for larazotide and we currently anticipate interim analysis in the second quarter of 2022. In the third quarter of 2021, we announced our collaboration with the European Biomedical Research Institute of Salerno, Italy ("EBRIS") to study larazotide for the treatment of MIS-C and EBRIS initiated a Phase 2a study in the fourth quarter of 2021. NM-102 and NM-004 are being evaluated in ongoing IND-enabling studies in varying indications.

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.

Even 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.

Many of these clinical, regulatory and commercial matters are beyond our control and are subject to the 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.

The COVID-19 pandemic has and may continue to materially and adversely affect our business and operations.

The COVID-19 pandemic has adversely impacted hospitals and medical facilities where we are currently conducting our Phase 2 VIBRANT clinical trial for vurolenatide and Phase 3 CeDLara clinical trial for larazotide. The evolving COVID-19 pandemic has created significant delays for our clinical trials primarily due to multiple site closures because of infected staff and due to patients avoiding or being unable to travel to healthcare facilities and physicians' offices unless due to a health emergency. The exact duration of these delays and any other impacts will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the COVID-19 outbreak, the spread of more transmissible variants, such as the Delta and Omicron variants, and the reduction in vaccine efficacy against new variants, the potential for future "shelter in place" orders, the severity of COVID-19, or the effectiveness of actions to contain and treat COVID-19. The continued spread of COVID-19 also has and we expect will continue to adversely impact our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, which could further negatively impact our trials. In addition, if the FDA elects to delay face-to-face meetings for an extended period of time due to COVID-19, it could have a material adverse effect on our Phase 3 CeDLara clinical trial and our other product candidates. Any or all of these events could increase our operating expenses and the length of time to complete our clinical trials and have a material adverse effect on our financial results.

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. As of the date of this report, we have 21 full-time employees, including 12 employees engaged full-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 to continue the development, regulatory approval and commercialization of our product candidates. We will need to hire or contract with additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing and sales and marketing. Additionally, 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 face 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 and attracting sufficiently skilled new 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 or to take on the duties necessary to continue growing our company and pursuing our business strategy. 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.

A breakdown or breach of our information technology systems or data security could subject us to liability, cybersecurity risks or interrupt the operation of our business.

Companies are subject to a wide variety of cybersecurity attacks on their information technology systems, which we use to maintain proprietary and confidential information. Our key business partners and third-party vendors face similar risks and any security breach of their systems could adversely affect our security posture. As a result of the COVID-19 pandemic, we are increasingly dependent upon information technology systems and data to operate our business. Our ability to effectively manage our business depends on the security, reliability and adequacy of our technology systems and data, which includes use of cloud technologies. Breakdowns, cyberattacks, corruptions, invasion, destruction, breaches of our technology systems or those of our business partners, unauthorized access to our data or other means to affect the confidentiality, integrity and availability of our technology systems and data could subject us to liability, negatively impact our business operations or require replacement of technology. Our technology systems and those of our partners continue to increase in multitude and complexity, increasing our vulnerability to cybersecurity risks. Data privacy or security breaches also pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to us, vendors or other business partners, may be exposed to unauthorized persons or to the public. Cyberattacks are increasing in their frequency and sophistication, and are becoming increasingly difficult to detect when they impact vendors, third-party partners or other companies in our supply chain.

In addition, our increased use of cloud technologies heightens these and other operational risks, and any failure by cloud or other technology service providers to adequately safeguard their systems and prevent cyberattacks could disrupt our operations and result in misappropriation, corruption or loss of confidential or propriety information. While we continue to build and improve our systems and infrastructure, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems. The loss of critical or sensitive information could result in financial, legal, operational or reputational harm to us, or loss of our competitive advantage. Our liability insurance may or may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches.

Failure to develop and maintain adequate financial controls could cause us to have material weaknesses, which could adversely affect our operations and financial position.

We might in the future discover material weaknesses that require remediation. In addition, an internal control system, no matter how well-designed, cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we might not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities.

Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations. Any failure to implement and maintain effective internal controls also could adversely affect the results of periodic management evaluations regarding the effectiveness of our internal control over financial reporting that we are required to include in our periodic reports filed

with the SEC under Section 404 of the Sarbanes-Oxley Act. Ineffective disclosure controls and procedures or internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. Implementing any appropriate changes to our internal controls may require specific compliance training of our directors, officers, and employees, entail substantial costs in order to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not be effective, however, in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. In the event that we are not able to demonstrate compliance with Section 404 of the Sarbanes-Oxley Act in a timely manner, that our internal controls are perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and our stock price could decline.

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 development programs. We engage consultants, advisors, clinical research organizations ("CROs"), contract manufacturing organizations ("CMOs") 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 Laboratory Practices ("GLP") or Good Clinical Practices ("GCP") 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 could adversely affect the development of our product candidates.

In addition, the third parties 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 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 manufacturers or a manufacturer'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 contracted with numerous clinical manufacturing organizations, or CMOs, making us highly dependent on these CMOs. For clinical and commercial supplies, if approved, we have or plan to have clinical supply agreements with third party CMOs for drug substance and finished drug product. While we have existing clinical supply agreements with third party CMOs, we would need to negotiate agreements for commercial supply with

several 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 CMOs to back up our primary vendors of clinical trial material or, if approved, commercial supply material. Identification of and discussions with other CMOs may be protracted and/or unsuccessful, or these new CMOs may be unsuccessful in producing the same results as the current primary CMOs producing the material. Therefore, if our primary CMOs 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 any product candidate for marketing and sale in the United States or abroad and securing such alternate manufacturer, if possible, 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 use the revised process.

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.

All manufacturers of our clinical trial material and, if approved, commercial product, including drug substance manufacturers, must comply with Good Manufacturing Practices (“GMP”) 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 GMP 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 GMP 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.

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. 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 materials and, if approved, commercial supply 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 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 in which we may 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 to implement on our own. Despite the experience of individual members of management, we have limited experience as a company 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. We recently hired a Chief Commercial Officer, who will lead our efforts to commercialize our robust pipeline of product candidates. Outside of the United States, we may consider collaboration arrangements. If we are unable to implement our own sales and marketing capability, or are unable to contract with one or more third parties for such services 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 or external 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.

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 or we may be required to change the way the product is administered, conduct additional clinical studies or change the labeling of the product. Depending on the severity of the side effects, regulatory authorities may withdraw approval of the product. 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 or any revenue from its sale.

In addition, in January 2021, we instituted an Expanded Access Program for Larazotide. Information obtained from our Expanded Access Program may not reliably predict the efficacy of our product candidates in company-sponsored clinical trials and may lead to adverse events that could limit our ability to obtain regulatory approval with labeling that we consider desirable, or at all.

Risks Related to Drug Development and Commercialization

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. Success in pre-clinical studies or completed clinical trials does not ensure that later studies or trials, including continuing pre-clinical studies and large-scale clinical trials, will be successful nor does it predict future results.

Favorable results in early studies or trials may not be repeated in later studies or trials, and product candidates in later stage trials may fail to show acceptable safety and efficacy despite having progressed through earlier trials. There is typically a high rate of attrition from the failure of product candidates proceeding through clinical trials. We may be required to demonstrate through large, long-term outcome trials that our product candidates are safe and effective for use in a broad population prior to obtaining regulatory approval.

In addition, the placebo rate in larger studies may be higher than expected and some participants in our clinical trials may respond positively to placebo treatment - these participants are commonly known as “placebo responders” - making it more difficult to demonstrate efficacy of the trial drug compared to placebo.

Further, clinical study data is frequently 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.

If any of our product candidates fail to demonstrate sufficient safety and efficacy in any clinical trial, we will experience potentially significant delays and cost increases in, or may decide to abandon development of, that product candidate. If we abandon or are delayed, or experience increased costs, in our development efforts related to any of our product candidates, we may not have sufficient resources to continue or complete development of that product candidate or any other product candidates. We may not be able to generate any revenues, continue our operations and clinical studies, or become profitable. Our reputation in the industry and in the investment community would likely be significantly damaged. Further, it might not be possible for us to raise funds in the public or private markets, and our stock price would likely decrease significantly.

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:

- delays in recruiting and enrolling individuals to participate in a clinical study, which historically can be challenging in orphan diseases, which is made more difficult during the COVID-19 pandemic;
- 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 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, which is made more difficult during the COVID-19 pandemic;
- 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.

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, if any, 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.

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 commence or 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:

- during the COVID-19 pandemic, the tendency of patients to avoid or their inability to travel to healthcare facilities and physicians' offices unless due to a health emergency;
- during the COVID-19 pandemic, healthcare site closures because of infected staff;
- 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;
- the frequency of or difficulty in administering our product candidates; and
- the ability to monitor patients adequately during and after treatment.

Use of our proprietary patient-reported outcome measure, CeD PRO, in our CeDLara Phase 3 clinical trial of larazotide might adversely impact our ability to achieve a positive result from this clinical trial.

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 CeDLara clinical trial of larazotide 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, and 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.

Significant uncertainty exists with respect to the regulatory approval process for any new drug candidate. 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. 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 our 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 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 our product candidates. In addition, regulations may be changed prior to submission of an NDA that require higher hurdles than currently anticipated. 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 our 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, or the FDA may delay face-to-face meetings for an extended period of time due to COVID-19, 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.

In 2019, we started the Phase 3 CeDLara clinical trial for larazotide, the success of which will be needed for FDA approval to market larazotide in the United States to treat CeD 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 larazotide. The results of this study will not be known until a short time prior to potential submission of an NDA for larazotide. 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 larazotide.

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 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.

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 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 programs, vurolenatide, for the treatment of SBS, and larazotide, for the treatment of CeD. 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.

We may choose not to continue developing any of our product candidates at any time during development and for any reason, which would reduce or eliminate our potential return on investment for those product candidates.

At any time, we may decide to discontinue the development of any of our product candidates for a variety of reasons, including inadequate financial resources, the appearance of new technologies that render our product candidates obsolete, competition from a competing product or changes in or failure to comply with applicable regulatory requirements. If we terminate a program in which we have invested significant resources, we will not receive any return on our investment and we will have missed the opportunity to allocate those resources to potentially more productive uses.

As an example, in connection with the merger with RDD and the acquisition of Naia in April 2020, and the subsequent acquisition of certain assets from Lobesity, LLC (“Lobesity”) in July 2021, we shifted our focus and cash resources to the development of larazotide, for treatment of CeD, vurolenatide for treatment of SBS, NM-136 for the treatment of rare obesity disorders, and NM-003, NM-102 and NM-004, three candidates for undisclosed rare and/or orphan diseases.

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. Our success will depend in part on our ability to:

- comply with the obligations of our existing and any future license agreements;
- 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 on and after March 16, 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 any of our product candidates that may be 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 product candidates, if approved, 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.

Larazotide, vurolenatide, NM-136, NM-003, and NM-004 are covered by several issued patents in the U.S., issued patents outside the U.S. and with patent applications pending in several jurisdictions. Intellectual property relating to the larazotide program is exclusively licensed from Alba Therapeutics Corp. (“Alba”). Additionally, we have collaborated with EBRIS to study larazotide for the treatment of MIS-C. Intellectual property relating to the vurolenatide and NM-003 programs, specifically the lead molecules GLP-1 and GLP-2 along with a related XTEN sequence, are exclusively licensed from Amunix Pharmaceuticals, Inc. (“Amunix”). Additionally, intellectual property for the rights to GLP-1 Agonist for the

treatment of SBS, related to the vurolenatide program, is licensed from Cedars-Sinai Medical Center ("Cedars"). Intellectual property relating to NM-004 program is exclusively licensed from Seachaid Pharmaceuticals Inc. ("Seachaid"). Intellectual property for the rights to a proprietary and highly specific humanized monoclonal antibody that targets glucose-dependent insulinotropic polypeptide, related to the NM-136 program were acquired from Lobesity. Our license agreements with Alba, Amunix, Cedars and Seachaid, and our asset purchase agreement with Lobesity 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, which loss may materially harm our business.

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 larazotide, vurolenatide, NM-136, NM-003 and NM-004. 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 larazotide 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 larazotide.

The patent prosecution process is expensive and time-consuming. We and any of our 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 of our 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 to develop, manufacture, receive approval for, market and sell our 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 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 product candidates, infringe, or that the use of our product candidates or technologies infringe.

We and our CMOs 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 product candidates or the use of our 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 product candidates, technologies or uses, or any of the underlying manufacturing processes, we could be required to pay damages and could be unable to commercialize our product candidates 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 product candidates or technology or those of our CMOs or component material suppliers or the use of our 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 product candidates or technologies, or those of our CMOs, or uses of our 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.

Our ability to successfully commercialize our products will depend in part on the extent to which governmental authorities, such as Medicare, private health insurers and other organizations establish what we believe to be appropriate coverage and reimbursement for our approved products. 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 any approved 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 products, there may be further uncertainty as to the adequacy of reimbursement amounts.

The containment of healthcare costs is a priority of federal, state and foreign governments and the prices of drug products have been a focus in this effort. The continuing efforts of government, private insurance companies and other organizations to contain or reduce costs of healthcare may adversely affect our ability to set as high a price for our products as we might otherwise and the rate and scope of adoption of our products by healthcare providers. 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.

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.

Any fast track designation or grant of priority review status by the FDA may not actually lead to a faster development or regulatory review or approval process, nor will it assure FDA approval of our product candidates. Additionally, our product candidates may treat indications that do not qualify for priority review vouchers.

We have received fast track designation for larazotide for the treatment of CeD. We may seek fast track designation for some of our other product candidates or priority review of applications for approval of our product candidates for certain indications. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. If a product candidate offers major advances in treatment, the FDA may designate it eligible for priority review. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for these designations, we cannot assure you that the FDA would decide to grant them. Even with the fast track designation for larazotide and if we do receive fast track designation or priority review for any other product candidate, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation from larazotide or any other product candidate to be so designated if it believes that the designation is no longer supported by data from our clinical development program.

Intense competition might render our gastroenterology products noncompetitive or obsolete.

Competition in the pharmaceutical industry in general and in our therapeutic sectors in particular 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 our gastroenterology product candidates and could have a material adverse effect on our 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 gastroenterological diseases and conditions addressed by our product pipeline. Developments by others might render our product pipeline obsolete or noncompetitive. Competitors might be able to complete the development and regulatory approval process sooner and, therefore, market their gastroenterology products earlier than we can.

Many of our current competitors have significant financial, marketing and personnel resources and development capabilities. For example, many large, well-capitalized companies already offer gastroenterology products and services in the United States and Europe that target the indications for: (i) SBS including acid suppressive therapies such as H2 blockers or proton pump inhibitors; antidiarrheals such as loperamide; antibiotics to prevent small intestinal bacterial overgrowth; octreotide for patient with IV fluid requirements greater than 3 liters 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; and (ii) CeD including methods to improve adherence to a gluten-free diet.

We might not receive all of the anticipated market exclusivity benefits of orphan drug designations.

Vurolenatide, a long-acting injectable GLP-1 analogue being developed for SBS and NM-003, a long-acting glucagon-like receptor-2 agonist that utilizes our proprietary XTEN technology to extend circulating half-life for the prevention of acute graft versus host disease, have each received Orphan Drug Designation from the FDA. Orphan Drug Designation may provide market exclusivity in the U.S. for seven years if (1) vurolenatide receives market approval before a competitor using a similar mechanism 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.

NM-003, NM-102 and NM-004 are being evaluated for development in other rare and/or orphan indications via an ongoing probability of technical and regulatory success analysis.

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.

We face potential product liability exposures, and if successful claims are brought against us, we may incur substantial liability for a 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 product candidates. 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;
- 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;
- decreased demand for our products, if approved, and loss of revenue; and
- the inability to commercialize our product candidates and any approved products.

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

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

Risks Related to Our Common Stock

The market price of our common stock 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”, and later under “NMTR”, on February 1, 2018, through March 22, 2022, the price thereof has ranged from a low of $0.37 per share to a high of $50.50 per share. 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 changes to or delays in clinical trials of our product candidates;
- announcements of regulatory approval or disapproval of, or delays in clinical trials for, larazotide (for CeD) or vurolenatide (for SBS) 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 COVID-19 pandemic; and
- the other factors described in this "Risk Factors" section.

The stock market in general has experienced relatively large price and volume fluctuations, particularly in response to the COVID-19 pandemic. 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.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to our existing stockholders.

Additionally, as of December 31, 2021, we had exercisable outstanding options and warrants (excluding out-of-the-money stock options and warrants) that if exercised would result in the issuance of 29.3 million shares of our common stock. Further, we are authorized to grant equity awards, including stock grants and stock options, to our employees, directors and consultants. As of December 31, 2021, there were 5,478,787 shares available for future issuance under the 2012 Omnibus Incentive Plan, as amended (the "2012 Plan"). During the term of the 2012 Plan, the share reserve will automatically increase on the first trading day in January of each calendar year, by (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 of directors. On January 1, 2022, on the terms of the 2012 Plan, an additional 12,911,771 shares were made available for issuance.

We expect to issue from time to time additional shares of our common stock and/or securities convertible into shares of our common stock to fund our operations and incentivize our employees and directors. In any such issuance, our stockholders would experience dilution and the market price of our common stock may decline.

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.

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain this listing, we must satisfy minimum financial and other requirements. On February 8, 2022, we received a notification letter from Nasdaq's Listing Qualifications Department indicating that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), because the minimum bid price of our common stock on The Nasdaq Capital Market closed below $1.00 per share for 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days to regain compliance with the minimum bid price requirement, or until August 8, 2022. To regain compliance, the closing bid price of our common stock has to meet or exceed $1.00 per share for at least ten consecutive business days before August 8, 2022.

While we intend to engage in efforts to maintain compliance, and thus maintain our listing, there can be no assurance that we will continue to meet all applicable Nasdaq Capital Market requirements in the future. If our common stock were removed from listing with The Nasdaq Capital Market, it may be subject to the so-called "penny stock" rules. The SEC has adopted regulations that define a "penny stock" to be any equity security that has a market price per share of less than $5.00, subject to certain exceptions, such as any securities listed on a national securities exchange, which is the exception on which we currently rely. For any transaction involving a "penny stock," unless exempt, the rules impose additional sales practice requirements on broker-dealers, subject to certain exceptions. If our common stock were delisted and determined to be a "penny stock," a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock on the secondary market.

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.

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 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 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;
- allow amendment of certain provisions of our amended and restated certificate of incorporation and our bylaws only by the vote of the holders of at least two-thirds of all then-outstanding shares of our common stock;
- grant the board of directors 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 of directors, 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. The 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 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 our earnings and financial condition and other business and economic factors affecting us at such time as the board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on investment will only occur if our stock price appreciates.

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.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our main office is located in Raleigh, North Carolina, where we lease approximately 2,751 square feet of office space under a lease that expires on September 30, 2024. The lease contains a three-year renewal option.

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

Item 3. Legal Proceedings.

We are not currently a party to any legal or governmental regulatory proceedings, nor is our management 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. In the future, we may from time to time become involved in litigation relating to claims arising from our ordinary course of business.

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

Our common stock has traded on the Nasdaq Capital Market under the trading symbol "NMTR" since May 2020. Prior to that time, our stock traded under the trading symbol "INNT" from January 29, 2018 through April 2020, and under the trading symbol "MSDI" from July 7, 2016 to January 29, 2018. Prior to July 7, 2016, there was no public market for our common stock.

Holders

As of March 18, 2022, there were approximately 270 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 of directors 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

None.

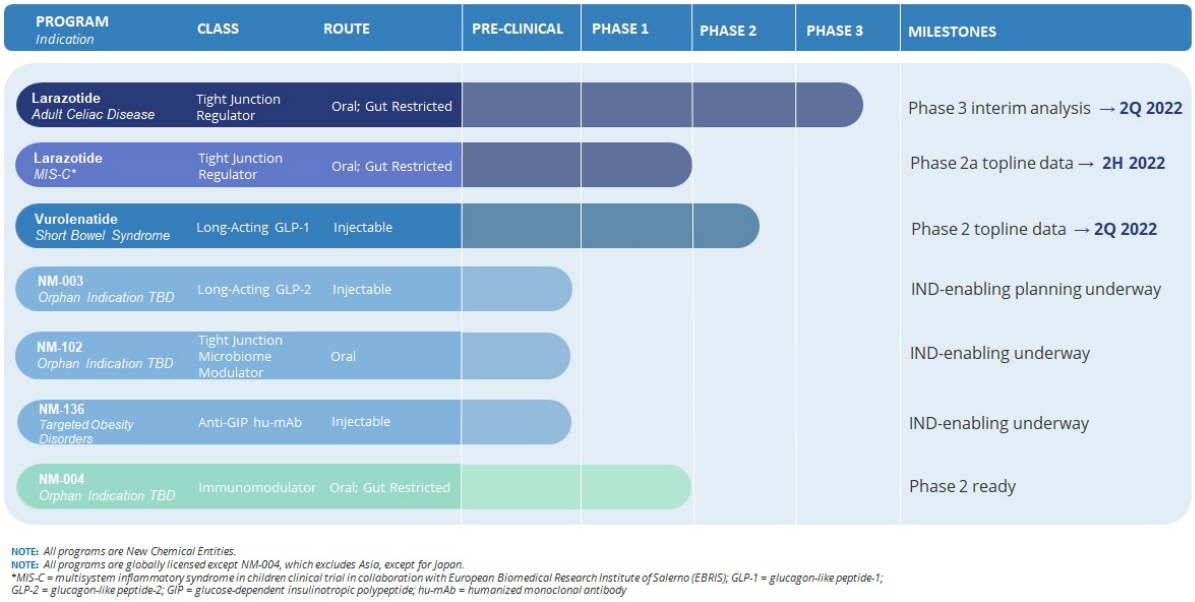
Item 6. Reserved.

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

The following discussion of our financial condition and results of operations should be read in conjunction with our audited consolidated 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.

Overview

9 Meters is a clinical-stage company pioneering novel treatments for people with rare digestive diseases, gastrointestinal conditions with unmet needs, and debilitating disorders in which the biology of the gut is a contributing factor. Our pipeline includes drug candidates for short bowel syndrome ("SBS"), celiac disease ("CeD"), multi-system inflammatory syndrome in children ("MIS-C") and a robust pipeline of early-stage candidates for undisclosed rare diseases and/or unmet needs. Our current product development pipeline is described in the table below:



NOTE: *All programs are New Chemical Entities.*
NOTE: *All programs are globally licensed except NM-004, which excludes Asia, except for Japan.*
**MIS-C = multisystem inflammatory syndrome in children clinical trial in collaboration with European Biomedical Research Institute of Salerno (EBRIS); GLP-1 = glucagon-like peptide-1; GLP-2 = glucagon-like peptide-2; GIP = glucose-dependent insulinotropic polypeptide; hu-mAb = humanized monoclonal antibody*

Vurolenatide for the Treatment of Short Bowel Syndrome

Vurolenatide is a long-acting injectable glucagon-like-peptide-1 ("GLP-1") analogue being developed for SBS, a debilitating orphan disease with an underserved market. It affects up to 20,000 adults in the U.S., with similar prevalence in Europe. Patients with SBS cannot absorb enough water, vitamins, protein, fat, calories and other nutrients from food. It is a severe disease with life-changing consequences, such as impaired intestinal absorption, diarrhea and metabolic complications. A portion of patients have life-long dependency on Parenteral Support (PS) to survive with risk of life-threatening infections and extra-organ impairment. Vurolenatide links exenatide, a GLP-1 analogue, to a long-acting linker technology and is designed specifically to address the gastric effects in SBS patients by slowing digestive transit time. The asset uses proprietary XTEN® technology to extend the half-life of exenatide, allowing for weekly to every other week dosing, thus potentially increasing convenience for patients and caregivers. Vurolenatide is patent-protected and has received orphan drug designation by the U.S. Food and Drug Administration ("FDA").

We announced top-line results from our Phase 1b/2a clinical trial for vurolenatide in SBS in the fourth quarter of 2020. The study met its primary objective as vurolenatide demonstrated excellent safety and tolerability. In addition, vurolenatide demonstrated a clinically relevant improvement in total stool output (TSO) volume within 48 hours of first dose. The Phase 1b/2a clinical trial was an open-label, two-dose study evaluating the safety and tolerability of three escalating fixed doses of vurolenatide (50 mg, 100 mg, 150 mg) in 9 adults with SBS for 56 days. The trial was conducted at Cedars-Sinai Medical

Center. Patients in each of the three cohorts received two subcutaneous doses two weeks apart with six weeks of subsequent follow-up. The study assessed the safety and tolerability of repeated doses on Days 1 and 15 at each dose level. Because reduced TSO volume and bowel movement frequency are correlated with improved intestinal absorption and potentially less need for intravenous supplementation for nutrition and hydration, these were key secondary objectives in the trial. The primary purpose of this open-label Phase 1b/2a trial was to assess the compound's safety and potential efficacy in order to inform future development.

Vurolenatide was generally safe and well tolerated: 17 treatment-emergent adverse events (TEAEs) were observed in 9 patients, 15 of which were mild, transient and self-limited without further intervention. The majority of TEAEs were GI-related (nausea and vomiting).

Importantly, 8 of the 9 patients experienced meaningful declines in TSO following each dose, relative to a baseline output. The rapid onset of clinical improvements in stool volumes, as observed in all 9 patients having substantial reductions in stool output within 48 hours of the first dose, shows the potential for vurolenatide to address the primary problem of chronic malabsorptive diarrhea in SBS patients. Additionally, four of seven patients showed reductions in bowel movement frequency after one dose and five of six evaluable patients showed reductions in bowel movement frequency after the second dose. Furthermore, of the five patients on PS in the trial, two patients showed reduction in PS after each dose. Results of the short-form health survey quality of life instrument demonstrated directional improvement in multiple elements of health status over the course of the trial. The short-form health survey, or SF-36, is a set of generic, coherent and easily administered quality-of-life measures. These measures rely upon patient self-reporting and are now widely utilized by managed care organizations and by Medicare for routine monitoring and assessment of care outcomes in adult patients.

We launched a multi-center, double-blind, double-dummy, randomized, placebo-controlled Phase 2 trial of vurolenatide for the treatment of SBS in the second quarter of 2021 using TSO as the primary efficacy outcome measure. The FDA has provided global anchor questions and specific guidance for performance of exit interviews to support clinical meaningfulness of observed efficacy. We anticipate topline results from the Phase 2 trial in the second quarter of 2022 followed by an End-of-Phase 2 meeting with the FDA. Shortly after our End-of-Phase 2 meeting with the FDA, we plan to initiate the Phase 3 trial.

Vurolenatide has received Orphan Drug Designation from the FDA. The FDA Office of Orphan Products Development grants orphan designation to advance the evaluation of safe and effective drugs and biologics to treat, prevent or diagnose rare diseases affecting fewer than 200,000 people in the U.S. Under the Orphan Drug Act, orphan designation qualifies drug sponsors for development incentives conferred by the FDA, including tax credits for qualified clinical testing.

Larazotide for Celiac Disease

In 2019, we initiated a Phase 3 clinical trial ("CeDLara") for our co-lead drug candidate, larazotide, for the treatment of CeD. Larazotide has the potential to be a first-to-market therapeutic for CeD, an unmet medical need affecting an estimated 1% of the U.S. population or more than 3 million individuals. Patients with CeD 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 CeD, larazotide is the only drug which has successfully met its primary clinical efficacy 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 CeD 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.

We have over 100 active clinical trial sites in our Phase 3 trial with three treatment groups, 0.25 mg of larazotide, 0.5 mg of larazotide and a placebo arm. In addition, after consultation with the FDA, the analytical approach to the primary endpoint was modified to perform a continuous variable analysis instead of a responder analysis of the primary efficacy outcome. The new methodology enables a more capital-efficient study, with reduction in participants from 630 to 525. Site activation and patient enrollment have been impacted by the COVID-19 pandemic. We continue to monitor the evolving situation with COVID-19, which is likely to impact the pace of enrollment directly or indirectly over the next several months. Interim results are anticipated in the second quarter of 2022. During 2021, we engaged Beyond Celiac and The Celiac Disease Foundation, both leading non-profit patient advocacy groups, to further identify potential and appropriate patients for enrollment in the Phase 3 trial. We also launched a CeD trial awareness campaign utilizing a dedicated YouTube channel and initiated a social media geo-targeting CeDLara awareness campaign. In October 2021, we held a live/virtual investigators'

meting directed toward enhancing enrollment efforts. We continue to evaluate and respond to trial execution challenges related to the ongoing COVID-19 pandemic and will implement additional measures as needed.

NM-003 Long-Acting GLP-2

NM-003 is a proprietary long-acting glucagon-like-peptide (“GLP-2”) receptor agonist with improved serum half-life compared with short-acting versions. On December 9, 2020, we announced that the FDA has granted orphan drug designation to NM-003 for prevention of acute graft versus host disease. NM-003, also called teduglutide, utilizes proprietary XTEN technology to extend circulating half-life. NM-003 is currently undergoing a preclinical proof-of-concept study. Based on the results of this study, we intend to progress NM-003 through a clinical and regulatory pathway in an undisclosed orphan and rare GI indication.

NM-102 Tight Junction Microbiome Modulator

NM-102, a small molecule peptide, is being developed as a potential microbiome modulator and undergoing an indication selection process. NM-102 is a long-acting, degradation-resistant peptide, believed to be gut-restricted, and presumed to prevent gut microbial metabolites and antigens from trafficking into systemic circulation. We recently announced a collaboration with Gustav Roussy, a leading cancer center in Villejuif, France, using NM-102. This collaboration adds to an initial 14-month preclinical research project initiated in March 2019, which focused on the relationship between intestinal microbiome composition and systemic responses to cancer treatments such as chemotherapy and immune checkpoint inhibitors.

NM-136 Humanized Monoclonal Antibody

On July 19, 2021, we entered into and closed an Asset Purchase Agreement with Lobesity LLC (“Lobesity”), pursuant to which we acquired global development rights to a proprietary and highly specific humanized monoclonal antibody, now known as NM-136, that targets glucose-dependent insulinotropic polypeptide (“GIP”), as well as the related intellectual property (the "Lobesity Acquisition"). GIP is a hormone found in the upper small intestine that is released into circulation after food is ingested, and when found in high concentrations, can contribute to obesity and obesity-related disorders such as Prader-Willi Syndrome. NM-136 has been shown to prevent GIP from binding to its receptor, which in preclinical obesity models has been shown to significantly decrease weight and abdominal fat by reducing nutrient absorption from the intestine as well as nutrient storage without affecting appetite. We have initiated antibody profiling to support a preclinical development program and expect to have a pre-IND meeting by the end of 2022.

NM-004 Immunomodulator

NM-004 is a double-cleaved mesalamine with an immunomodulator. NM-004 is currently undergoing a probability of technical, regulatory and intellectual property analysis in an undisclosed GI indication. Based on the results of that analysis, we intend to determine the viability of a path forward.

Corporate Development

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

On October 6, 2019, we entered into an Agreement and Plan of Merger and Reorganization pursuant to which we agreed to acquire all of the outstanding capital stock of privately-held RDD Pharma, Ltd., an Israel corporation (“RDD”), in exchange for common stock issued by us to the existing RDD shareholders (the “RDD Merger”). The RDD Merger closed on April 30, 2020. In connection with the RDD Merger, we changed our name from Innovate Biopharmaceuticals, Inc. to 9 Meters Biopharma, Inc.

RDD Merger Financing

On April 29, 2020, we entered into a securities purchase agreement with various accredited investors, pursuant to which we agreed to issue and sell to the investors units (“Units”) consisting of (i) one share of Series A Convertible Preferred Stock (the "Series A Preferred Stock") and (ii) one five-year warrant (the "Preferred Warrants") to purchase one share of Series A Preferred Stock (the “RDD Merger Financing”). On May 4, 2020, we closed the RDD Merger Financing and sold an

aggregate of (i) 382,779 shares of Series A Preferred Stock, which converted into 38,277,900 shares of common stock on June 30, 2020, upon receipt of approval by our stockholders (the "Automatic Conversion"), and (ii) Preferred Warrants to purchase up to 382,779 shares of Series A Preferred Stock, which, following the Automatic Conversion, became exercisable for 38,277,900 shares of common stock. The exercise price of the Preferred Warrants was $58.94 per share of Series A Preferred Stock, and following the Automatic Conversion, became $0.5894 per share of common stock, subject to adjustments as provided under the terms of the Preferred Warrants. In addition, broker warrants covering 8,112 Units and broker warrants covering 10,899 shares of Series A Preferred Stock, which, following the Automatic Conversion, became exercisable for 2,712,300 shares of common stock, were issued in connection with the RDD Merger Financing. Gross proceeds from the RDD Merger Financing were approximately $22.6 million with net proceeds of approximately $19.2 million after deducting commissions and estimated offering costs.

Naia Acquisition

On May 6, 2020, we entered into and consummated a two-step merger with Naia Rare Diseases, Inc. in accordance with the terms of an Agreement and Plan of Merger (the "Naia Acquisition"). The consideration for the Naia Acquisition at closing consisted of $2.1 million in cash and 4,835,438 shares of common stock valued at $2.2 million, plus the pre-payment of certain operating costs on behalf of Naia totaling $0.1 million. Consideration for the Naia Acquisition also included potential future development and sales milestone payments worth up to $80.4 million and royalties on net sales of certain products to which Naia has exclusive rights by license. No contingent consideration for the Naia Acquisition was recorded at the time of acquisition because the potential development and sales milestones were not deemed probable.

Lobesity Acquisition

On July 19, 2021, we completed an Asset Purchase Agreement with Lobesity, pursuant to which we acquired global development rights to a proprietary and highly specific humanized monoclonal antibody, NM-136, that targets GIP, as well as the related intellectual property. We paid a combination of cash and equity consideration in the form of a $5 million upfront payment, as 40% cash and 60% equity (consisting of 2,417,211 shares of unregistered common stock priced at our 3-day volume weighted-price immediately prior to the closing), plus the right to contingent payments including certain potential worldwide regulatory and clinical milestone payments totaling $45.5 million for a single indication (with the total amount payable, if multiple indications are developed, not to exceed $58.0 million), global sales-related milestone payments totaling up to $50.0 million, and, subject to certain adjustments, a mid-single digit royalty on worldwide net sales.

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. To date, we have financed our operations primarily through public offerings of equity securities and private placements of convertible debt and equity securities.

As of December 31, 2021, we had an accumulated deficit of $168.8 million. We incurred net losses of $36.8 million and $61.5 million for the years ended December 31, 2021 and 2020, 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 larazotide and vurolenatide;
- experience delays in our clinical trials due to the COVID-19 pandemic;
- successfully develop acquired clinical assets
- 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;
- pursue additional in- or out-licenses or similar strategic transactions; 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.

COVID-19

The effect of the COVID-19 pandemic and its associated restrictions, including the recent Omicron variant, has delayed and may continue to delay the expected development timelines and may increase the anticipated aggregate costs for our product candidates. Impacts from the COVID-19 pandemic include, but are not limited to, disruptions in the supply chain for clinical supplies, delays in the timing and pace of participant enrollment in clinical trials and lower than anticipated participant enrollment and completion rates due to COVID-19 clinical site closures, delays in the review and approval of our regulatory submissions by the FDA and other agencies with respect to our product candidates, and other unforeseen disruptions. Site activation and patient enrollment have been impacted by the COVID-19 pandemic and could continue to be impacted by the pandemic over the next several months. We are working closely with our clinical trial sites and product candidate manufacturers to ensure that patient safety and clinical supply of our product candidates are not adversely impacted by the pandemic, while also attempting to progress our trials and product candidate development as much as we can. In response to the COVID-19 pandemic, we put in place several safety measures for our employees, patients, healthcare providers and suppliers. These measures included, but were not limited to, substantially restricting travel, limiting access to our corporate office, including allowing employees to work remotely, providing personal protective equipment to employees, investigator sites and third-party vendors, implementing social distancing protocols, and coordinating safety protocols with our investigator sites.

The ultimate impact resulting from the COVID-19 pandemic will depend, among other factors, on the extent of the pandemic in the regions with clinical trial sites, the timing and availability of the COVID-19 vaccines and length and severity of travel restrictions and other limitations ordered by governmental agencies. New and potentially more contagious variants could further affect the impact of the COVID-19 pandemic on our operations.

The economic impact of the COVID-19 pandemic and its effect on capital markets and investor sentiment may adversely impact our ability to raise capital when needed or on acceptable terms to fund our development programs and operations. However, we closed public offerings and received net proceeds of approximately $31.5 million in April 2021 and $32.0 million in December 2020, which we plan to use to complete the Phase 2 trial vurolenatide in SBS and continue progression of our Phase 3 larazotide trial in CeD. In addition, we have a robust pipeline of early-stage product candidates, including recently acquired NM-136.

We do not yet know the full extent of potential delays or impacts on our business, clinical trial activities, ability to access capital or on healthcare systems or the global economy as a whole due to the COVID-19 pandemic. However, these effects could have a material adverse impact on our business and financial condition.

Results of Operations

Comparison of the Years Ended December 31, 2021 and 2020

The following table sets forth the key components of our results of operations for the years ended December 31, 2021 and 2020:

	Year Ended December 31,			
	2021	2020	$ Change	% Change
Operating expenses:				
Research and development	$ 21,995,291	$ 10,933,023	$ 11,062,268	101 %
Acquired in-process research and development	5,103,753	32,266,893	(27,163,140)	(84)%
General and administrative	9,662,875	10,519,955	(857,080)	(8)%
Warrant inducement expense	—	7,157,887	(7,157,887)	(100)%
Total operating expenses	36,761,919	60,877,758	(24,115,839)	(40)%
Loss from operations	(36,761,919)	(60,877,758)	24,115,839	40 %
Total other income (expense), net	(17,481)	(618,731)	601,250	97 %
Net loss	$ (36,779,400)	$ (61,496,489)	$ 24,717,089	40 %

Research and Development Expense

Research and development expense for the year ended December 31, 2021 increased approximately $11.1 million, or 101%, as compared to the year ended December 31, 2020. The increase was primarily due to an increase of approximately $5.6 million in clinical trial expenses associated with completion of the Phase 1b trial and launching of the Phase 2 trial in SBS. In addition, expenses associated with our other pipeline drugs increased by approximately $3.9 million for the Phase 3 trial in CeD, $1.7 million for IND-enabling activities for NM-102 and $1.0 million for preclinical development of NM-136. Personnel costs and benefits increased by approximately $1.5 million due to the addition of research and development personnel during the year ended December 31, 2021. These increases were offset by a decrease in research and development license fees of approximately $1.6 million and a decrease in non-cash share-based compensation expense of approximately $1.0 million. The accelerated vesting of certain outstanding options upon closing of the RDD Merger in 2020 and additional options awarded in 2020, some of which were fully vested upon grant as a non-cash merger bonus, contributed to non-cash share-based compensation expense being higher in 2020. The table below summarizes our research and development expenses by program, license fees and other research and development expenses for the periods indicated.

	Year Ended December 31,	
	2021	2020
Research and development expenses:		
Larazotide - Celiac Disease	$ 7,484,835	$ 3,634,291
Vurolenatide - Short Bowel Syndrome	7,419,098	1,772,388
NM-102 - Orphan Indication	1,728,513	—
NM-136 - Obesity Disorder	1,020,748	—
License fees	600,000	2,201,985
Other research and development expenses	3,742,097	3,324,359
Total research and development expenses	$ 21,995,291	$ 10,933,023

Acquired In-process Research and Development

Acquired in-process research and development expense was approximately $5.1 million for the year ended December 31, 2021 as compared to $32.3 million for the year ended December 31, 2020. Acquired in-process research and development expense during the year ended December 31, 2021 represents expenses associated with the Lobesity Acquisition and includes approximately $2.6 million non-cash acquired in-process research and development expense paid in equity ownership. Acquired in-process research and development expense during the year ended December 31, 2020 represents expenses associated with the RDD Merger and Naia Acquisition. Approximately $28.8 million represents non-cash acquired in-process research and development expense paid in equity ownership.

General and Administrative Expense

General and administrative expense for the year ended December 31, 2021 decreased by approximately $0.9 million, or 8%, as compared to the year ended December 31, 2020. The decrease was primarily due to decreases in (i) non-cash stock compensation expense of approximately $1.3 million, (ii) personnel costs and benefits of approximately $0.2 million, (iii) costs associated with operating as a public company of $0.4 million, and (iv) professional fees of $0.3 million. The accelerated vesting of certain outstanding options upon closing of the RDD Merger in 2020 and additional options awarded in 2020, some of which were fully vested upon grant as a non-cash merger bonus, contributed to non-cash share-based compensation being higher in 2020. Personnel costs and benefits was higher in 2020 due to severance expense related to the termination of former Innovate employees upon closing of the RDD Merger. These decreases were offset by increases in general corporate fees, including patent protection of our intellectual property, market research and business development of approximately $1.3 million.

Warrant Inducement Expense

During the year ended December 31, 2020, we recognized warrant inducement expense of approximately $7.2 million. 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 and to induce the exercise of certain warrants in the Offer to Amend and Exercise, further described in “Note 1—Summary of Significant Accounting Policies” to the accompanying consolidated financial statements included in this Annual Report on Form 10-K. There was no warrant inducement expense during the year ended December 31, 2021.

Other Income (Expense), Net

Other expense, net, for the year ended December 31, 2021, decreased by approximately $0.6 million, or 97%, as compared to the year ended December 31, 2020. The change in other expense consists of a decrease in interest expense of approximately $4.0 million, which includes the non-cash beneficial conversion feature of $2.2 million associated with our convertible note. This decrease was offset by the decrease in other income related to the prior year gain on fair value of warrant liabilities of approximately $2.6 million and the gain on fair value of derivative liability of approximately $0.8 million.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2021, we had cash and cash equivalents of approximately $47.0 million, compared to approximately $37.9 million as of December 31, 2020. The increase in cash and cash equivalents was primarily due to the net proceeds of $31.5 million received in the public offering of common stock that closed in April 2021. In addition, the Company received proceeds of approximately $9.2 million from the exercise of warrants and approximately $0.3 million from the exercise of stock options during the year ended December 31, 2021. These increases in cash were offset by expenditures for business operations, research and development and clinical trial costs, including the launch of the Phase 2 clinical trial in SBS and the Lobesity Acquisition.

To date, we have not generated revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. 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 and eventually

commercialize our product candidates. Our future liquidity and capital requirements will depend on a number of factors, including the outcome of our clinical trials, which could be delayed due to the ongoing COVID-19 pandemic, and our ability to complete the development and commercialization of our products. There are a number of variables beyond our control including the timing, success and overall expense associated with our clinical trials. Consequently, there can be no assurance that we will be able to achieve our objectives and we will need to seek additional funding. 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. We continue to evaluate multiple dilutive and non-dilutive sources for future funding. If we raise additional funds through the issuance of equity securities, substantial dilution to our existing shareholders could occur. We have concluded that the prevailing conditions and ongoing liquidity risks faced by us raise substantial doubt about our ability as a going concern.

Cash Flows

The following table sets forth the primary sources and uses of cash for the years ended December 31, 2021 and 2020:

	Year Ended December 31,	
	2021	**2020**
Net cash (used in) provided by:		
Operating activities	$ (29,478,275)	$ (19,409,786)
Investing activities	(2,430,641)	(3,186,997)
Financing activities	41,050,813	55,855,239
Net increase in cash and cash equivalents	$ 9,141,897	$ 33,258,456

Operating Activities

For the year ended December 31, 2021, net cash used in operating activities of approximately $29.5 million primarily consisted of a net loss of $36.8 million, offset by adjustments for non-cash share-based compensation of approximately $2.4 million, amortization of debt discount of less than $0.1 million and non-cash in process research and development expense of approximately $2.6 million. In addition, the net change in operating assets and liabilities increased by approximately $2.2 million.

For the year ended December 31, 2020, net cash used in operating activities of approximately $19.4 million primarily consisted of a net loss of $61.5 million, a non-cash gain of $2.6 million for the change in the fair value of the warrant liabilities and a non-cash gain of approximately $0.8 million for the change in fair value of the convertible note derivative liabilities. These decreases were offset by adjustments for non-cash share-based compensation of approximately $4.7 million, non-cash warrant inducement expense of $7.2 million, non-cash interest expense of approximately $1.8 million, a non-cash beneficial conversion feature of approximately $2.2 million associated with the conversion of convertible note principal and interest, and non-cash in process research and development expense of approximately $28.8 million. In addition, the net change in operating assets and liabilities increased by approximately $0.8 million.

Investing Activities

For the year ended December 31, 2021, net cash used in investing activities represents the purchase of property and equipment of approximately $12,000 and the purchase of in-process research and development, net of assets received, of approximately $2.5 million. These cash outflows were offset by the maturity of our restricted investment of $75,000. Net cash used in investing activities for the year ended December 31, 2020 represented the purchase of property and equipment of approximately $2,500 and the purchase of in-process research and development, net of assets received, of approximately $3.2 million.

Financing Activities

For the year ended December 31, 2021, net cash provided by financing activities of approximately $41.1 million primarily consisted of (i) proceeds of $34.5 million from the public offering of our common stock that closed in April 2021, (ii) proceeds $9.2 million from the exercise of warrants and (iii) proceeds of $0.3 million from the exercise of stock options. These increases were offset by approximately $0.1 million in debt repayments and approximately $2.9 million in stock issuance costs.

For the year ended December 31, 2020, net cash provided by financing activities of approximately $55.9 million primarily consisted of (i) $37.1 million received from the sale of our common stock and warrants; (ii) proceeds of $22.6 million from the issuance of preferred stock and warrants in the RDD Merger Financing, (iii) proceeds of $2.5 million from the issuance of the unsecured convertible promissory note issued in January 2020 and (iv) proceeds of approximately $2.5 million from the exercise of warrants. These increases were offset by approximately $2.5 million in debt repayments and approximately $6.4 million in stock issuance costs.

Contractual Obligations and Commitments

In July 2020, we entered into a four-year lease agreement for office space that expires on September 30, 2024. Base annual rent for the four-year lease period is $72,000 with monthly rent payments of $6,000.

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.

Periodically, we enter into separation and general release agreements with former executives that include separation benefits consistent with the former executive's employment agreements. We recognized severance expense totaling $0.4 million and $0.8 million during the years ended December 31, 2021 and 2020, respectively. Severance payments are made in equal installments over 12 months from the date of separation. The accrued severance obligation in respect of former executives is approximately $0.4 million as of December 31, 2021.

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. In general, the amount and timing of sub-license fees and the achievement and timing of development and commercialization milestones are not probable and estimable, and as such, these commitments have not been included on the accompanying consolidated balance sheets. During the years ended December 31, 2021 and 2020, we incurred development milestone fees of approximately $0.6 million and $2.2 million, respectively.

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.

Off-Balance Sheet Arrangements

As of December 31, 2021, 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 consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our consolidated 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 consolidated 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 consolidated 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 consolidated financial statements and understanding and evaluating our reported financial results.

Areas of our consolidated financial statements where estimates may have the most significant effect include acquired in-process research and development, 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.

Acquired In-process Research and Development Expense

We have acquired and may in the future acquire, rights to develop and commercialize new drug candidates and/or other in-process research and development assets. The up-front acquisition payments, as well as future milestone payments associated with asset acquisitions that are deemed probable to achieve the milestones and do not meet the definition of a derivative, are expensed as acquired in-process research and development provided that the drug has not achieved regulatory approval for marketing, and, absent obtaining such approval, have no alternative future use. See "Note 3—Merger and Acquisition" to our consolidated financial statements for further discussion of acquired in-process research and development expense during the years ended December 31, 2021 and 2020.

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 the grant of stock options to be recognized in the consolidated statements of operations based on the option's fair value at the grant date. Share-based compensation expense is generally recognized on a straight-line basis over the requisite service period for awards with time-based vesting. For awards with performance conditions, compensation cost is recognized from the time achievement of the performance criteria is probable over the remaining expected term.

We estimate the fair value of our stock-based awards 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. Due to limited history of stock option exercises, we estimate the expected term of stock options with service conditions based on the simplified method, which calculates the expected term as the average of the time-to-vesting and the contractual life of options. Pursuant to ASU 2018-07, we elected to use the contractual life of the option as the expected term for non-employee options. The expected term for performance options is the longer of the explicit or implicit service period.

Income Taxes

No provision for federal and state income tax expense has been recorded for the years ended December 31, 2021 and 2020 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, 2021, we had net operating loss carryforwards for federal, state and foreign income tax purposes of approximately $88,722,200, $88,568,100 and $30,689,600 respectively. Federal loss carryforwards of $3,551,900 begin to expire in 2034 and $85,170,300 of the federal losses carryforward indefinitely. The state loss carryforwards begin to expire in 2029. Foreign net operating losses carry forward indefinitely, and may be subject to limitation. As of December 31, 2021, we had contribution carryforwards of approximately $11,000, which begin to expire in 2023. In addition, we have federal research and development credits of $2,534,600, 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 or are currently being evaluated, see “Note 1—Summary of Significant Accounting Policies—Recently Issued Accounting Standards” to the accompanying consolidated 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, 2021. 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, 2021, our disclosure controls and procedures were effective in providing reasonable assurance that the information required to be disclosed by us in this report was accumulated and communicated in the manner provided above.

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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements would be prevented or detected.

In making the assessment of internal control over financial reporting, our management used the criteria issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control-Integrated Framework (2013)*. Based on our evaluation under the Internal Control-Integrated Framework, management concluded that our internal control over financial reporting was effective as of December 31, 2021.

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 continue to qualify as a "non-accelerated filer."

Changes in Internal Control Over Financial Reporting

There were no material changes in our internal control over financial reporting during the quarter ended December 31, 2021, that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

In July 2021, the Company entered into an amendment to the executive employment agreement, dated April 30, 2020, with our Chief Executive Officer, John Temperato. The amendment provided that if the employment of Mr. Temperato is terminated by the Company without "cause" or by Mr. Temperato for "good reason" within 12 months of a "change in control" (each as defined in the employment agreement, as amended, Mr. Temperato will be eligible to receive 18 months of his then-current salary, the amount of his target year-end annual non-equity incentive award, and accelerated vesting of all of his unvested options and restricted stock unit awards. All separation benefits are subject to Mr. Temperato entering into and not revoking a separation agreement. The remainder of his employment agreement remained in full force and effect.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Directors

The Board currently comprises six members, divided into three classes. Each class consists, as nearly as possible, of one-third of the total number of directors and each class has a three-year term. Each director in each class is elected for a term of three years and serves until a successor is duly elected and qualified or until his or her earlier death, resignation or removal. Any additional directorships resulting from an increase in the number of directors or a vacancy may be filled only by the directors then in office (as provided in our certificate of incorporation and bylaws). Because only one-third of our directors will be elected at each annual meeting, two consecutive annual meetings of stockholders could be required for the stockholders to change a majority of the Board.

Information about our directors, their ages as of March 18, 2022, 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 our Board at this time.

Director	Age	Class	Current Term Expiration
Michael Constantino	59	Class I	2022 Annual Meeting of Stockholders
Lorin K. Johnson, Ph.D.	69	Class I	2022 Annual Meeting of Stockholders
Michael Rice	57	Class II	2023 Annual Meeting of Stockholders
John Temperato	57	Class II	2023 Annual Meeting of Stockholders
Mark Sirgo, Pharm.D.	68	Class III	2024 Annual Meeting of Stockholders
Samantha Ventimiglia	49	Class III	2024 Annual Meeting of Stockholders

Michael Constantino. Mr. Constantino joined our Board in June 2020. Mr. Constantino is a retired Ernst & Young LLP assurance partner who served in the Research Triangle Park Region of North Carolina for over 30 years. From 2009 to 2012, he served as the Office Managing Partner for the combined Raleigh/Greensboro office with over 200 employees. He was responsible for leading a growing practice that included assurance, advisory and tax services focused on public and privately held entrepreneurial companies representing many industries. During his career with the firm, he worked with several companies including life sciences companies (biotechnology, medical device and pharmaceuticals), contract research organizations, technology, manufacturing and transportation companies, and large SEC registrants. Mike assisted clients with over 20 initial public offerings, debt offerings, mergers and acquisition transactions, and private equity offerings. He worked closely with companies across the development continuum from start-up to mature public entities and assisted management teams and boards of directors with SEC compliance matters, Sarbanes-Oxley internal controls, global operations and strategic planning. Currently, he is the Chair of the Audit Committee of Humacyte (Nasdaq:HUMA), a biotechnology company that is

pioneering the development and manufacture of off-the-shelf, universally implantable, bioengineered human tissues. Mike holds a B.A. in both Accounting and Business Management from NC State University and is a North Carolina CPA.

We believe that Mr. Constantino's extensive experience as a CPA and with SEC compliance matters and Sarbanes-Oxley internal controls qualifies him to serve on our Board.

Lorin K. Johnson, Ph.D. Dr. Johnson joined our Board in January 2018. He is the founder and Chief Scientist of Glycyx PharmaVentures Ltd., a biopharma investment and development company. In 1989, he co-founded Salix Pharmaceuticals, Inc. (Nasdaq: SLXP), a specialty pharmaceutical company specializing in gastrointestinal products, and held senior leadership positions prior to its $15.8 billion acquisition by Valeant Pharmaceuticals International, Inc. (NYSEA: VRX) in April 2015. Prior to Salix, Dr. Johnson served as Director of Scientific Operations and Chief Scientist at Scios, Inc. (formerly California Biotechnology, Inc). Since June 2019, he has been a board member of Edesa Biotech, Inc. (Nasdaq: EDSA), a biopharmaceutical company in the fields of inflammation, infectious disease and gastroenterology. He is also a board member of Glycyx MOR, Inc. (Delaware) and Kinisi Therapeutics, Ltd. (Isle of Man), as well as Intact Inc. (California). All are GI specialty drug development companies. 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 our Board.

Michael Rice. Mr. Rice joined our Board in February 2021. Mr. Rice is president and co-founder of LifeSci Advisors, LLC, a life sciences investor relations consultancy, and co-founder of LifeSci Capital, a research-driven investment bank, positions he has held since March 2010. Mr. Rice is also a founding member of LifeSci Communications, LLC, a corporate communications and public relations firm. From June 2019 to December 2020, Mr. Rice also served as Chief Operating Officer and a member of the board of LifeSci Acquisition Corp. until its merger with Vincerx Pharma, Inc. (f/k/a Vincera Pharma, Inc.). Prior to co-founding LifeSci Advisors and LifeSci Capital, Mr. Rice was the co-head of health care investment banking at Canaccord Adams from April 2007 to November 2008, where he was involved in debt and equity financing. Mr. Rice was also was a Managing Director at ThinkEquity Partners from April 2005 to April 2007, where he was responsible for managing Healthcare Capital Markets. Prior to that, from August 2003 to March 2005, Mr. Rice served as a Managing Director at Bank of America, serving large hedge funds and private equity healthcare funds. Previously, he was a Managing Director at JPMorgan/Hambrecht & Quist. Mr. Rice has been a director of Navidea, Biopharmaceuticals Inc. (NYSEA: NAVB) since May 2016 and served as a director of RDD from January 2016 until the Company's merger with RDD in May 2020. Michael received his B.A. from the University of Maryland. Michael holds Series 7, 24, 63, and 79 licenses.

We believe Mr. Rice's long-running healthcare investment and advisory experience qualifies him to serve on our Board.

John Temperato. Mr. Temperato joined our Board in April 2020 leading the creation of 9 Meters through a merger of three companies: Innovate Biopharmaceuticals, Inc., RDD Pharma Ltd., and Naia Rare Diseases, Inc in May of 2020. Prior to the merger, Mr. Temperato served as the Chief Executive Officer of RDD from March 2019 until April 2020. Prior to joining RDD, Mr. Temperato held various leadership roles, including most notably U.S. President & Chief Operating Officer with Atlantic Healthcare, President & Chief Operating Officer/Chief Commercial Officer with Melinta Therapeutics, Inc., and Senior Vice President of Sales and Managed Markets with Salix Pharmaceuticals, Inc., a specialty pharmaceutical company specializing in gastrointestinal products. Notably, at Salix Pharmaceuticals, Mr. Temperato played a critical role in the successful commercialization and growth of their broad GI portfolio and executed over ten launches during his tenure at the company driving growth of company revenues from $119 million in 2004 to $2 billion in 2015. Across his career, Mr. Temperato has been instrumental in defining and executing capital efficient go-to-market strategies, business development strategy and overseeing the commercialization and life-cycle management for small molecules, devices, and biologics. Additionally, he has developed strategies for reimbursement and external healthcare policy. He holds a Bachelor of Science degree from the University of Bridgeport in Bridgeport, Connecticut.

We believe that Mr. Temperato's extensive executive experience in the pharmaceutical and healthcare industries qualifies him to serve on our Board.

Mark Sirgo, Pharm.D. Dr. Sirgo joined our Board in April 2020 upon completion of the RDD Merger and was appointed as Board chairman. In January 2019, Dr. Sirgo was appointed Chief Executive Officer of Aruna Bio, Inc., a private development-stage company focused on central nervous system and neurodegenerative disorders. Dr. Sirgo serves as a director of BioDelivery Sciences International, Inc. (Nasdaq: BDSI), a position he has held since August 2005. He was President and Chief Executive Officer of BDSI from January 2005 to January 2018. He joined BDSI in August 2004 as Senior Vice President of Commercialization and Corporate Development upon its acquisition of Arius Pharmaceuticals, Inc., of which he was a co-founder and Chief Executive Officer. Dr. Sirgo has over 30 years of experience in the pharmaceutical industry, including senior and/or executive positions in research and development, business development, sales, marketing and business operations. Dr. Sirgo spent 16 years in a variety of positions of increasing responsibility in both clinical development and marketing at Glaxo, Glaxo Wellcome, and GlaxoSmithKline, including Vice President of International OTC Development and Vice President of New Product Marketing. From 1996 to 1999, Dr. Sirgo was Senior Vice President of Global Sales and Marketing at Pharmaceutical Product Development, Inc. (Nasdaq: PPDI), a leading contract service provider to the pharmaceutical industry. Dr. Sirgo served on the Board of Directors and as Chairman of the Compensation Committee of Salix Pharmaceuticals, Inc. (Nasdaq: SLXP), a specialty pharmaceutical company specializing in gastrointestinal products, from 2008 until its sale in 2015. In addition to his role on the Board of BDSI, Dr. Sirgo serves on the Board of Directors of Biomerica, Inc. (Nasdaq: BMRA), a gastrointestinal diagnostics and therapeutic company. Dr. Sirgo received his BS in Pharmacy from The Ohio State University and his Doctorate from Philadelphia College of Pharmacy and Science.

We believe that Dr. Sirgo's extensive executive level experience in the pharmaceutical industry qualifies him to serve on our Board.

Samantha Ventimiglia. Ms. Ventimiglia joined our Board in October 2021. Since December 2011, Ms. Ventimiglia has served in various leadership roles at Vertex Pharmaceuticals, Inc., a global biotechnology company, and is currently Senior Vice President, U.S. Public Affairs, responsible for developing and overseeing the company's policy, government affairs and patient advocacy strategy, including building relationships with state and federal government officials, industry organizations, patient groups and other stakeholders. From February 2008 until December 2010, Ms. Ventimiglia was government affairs director at Astellas Pharma US, a multinational pharmaceutical company, and from April 2004 until February 2008, she was a principal consultant at Jeffrey J. Kimbell & Associates, a federal government affairs firm representing clients in the healthcare community who are seeking legislative and regulatory solutions to problems related to product approval, coverage and reimbursement and marketing practices. Prior to that, Ms. Ventimiglia was a policy director at the Pharmaceutical Research & Manufacturers of America (PhRMA) and the National Governors Association (NGA) where she played a pivotal role in development the associations' policy and legislative agenda on Medicare, Medicaid, private sector healthcare and FDA issues. She also held legislative positions in the offices of U.S. Senator Olympia J. Snowe and U.S. Congressman Elton Gallegly. Ms. Ventimiglia received a B.A. from Catholic University of America and a Master of Public Policy from Georgetown University.

We believe that Ms. Ventimiglia's years of experience seeking legislative and regulatory solutions in the healthcare industry qualifies Ms. Ventimiglia to serve on our Board.

Executive Officers

For information regarding Mr. Temperato, our Chief Executive Officer, please see his biography above under "Directors."

Corporate Governance

Family Relationships

There is no family relationship between any director or executive officer of our Company.

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 Michael Constantino (Chair), Lorin K. Johnson, Ph.D. and Mark Sirgo, Pharm.D. Each member of our audit committee is independent in accordance with applicable SEC and Nasdaq rules. The Board has determined that Mr. Constantino 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 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 Overview" page of the "Investors" section of our website, which may be accessed by navigating to www.9meters.com/corporate-governance/. 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 Annual Report.

Item 11. Executive Compensation.

This Executive Compensation section describes the material elements of our compensation program for our "named executive officers" during 2021. Our named executive officers consisted of two individuals, our principal executive officer and our principal financial officer during 2021; there were no other executive officers of the Company during 2021. Our named executive officers for 2021 were:

- Mr. Temperato, who has served as our President and Chief Executive Officer (our "CEO") since April 2020; and
- Edward J. Sitar, who served as our Chief Financial Officer (our "Former CFO") from June 2019 through January 2022.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards[1] ($)	Option Awards[2] ($)	Non-equity Incentive Plan Compensation[3] ($)	All Other Compensation ($)	Total ($)
John Temperato	2021	$ 537,100	$ —	$ —	$ 1,435,854	$ 214,840	$ —	$ 2,187,794
President and Chief Executive Officer [4]	2020	$ 328,708	$ —	$ 326,577	$ 1,253,588	$ 159,375	$ —	$ 2,068,248
Edward J. Sitar	2021	$ 371,500	$ —	$ —	$ 523,489	$ 118,880	$ —	$ 1,013,869
Chief Financial Officer[5]	2020	$ 311,000	$ —	$ —	$ 381,810	$ 86,400	$ —	$ 779,210

(1) 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 the named executive officer upon the vesting of the restricted stock units or the sale of the common stock underlying the award.

(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 named executive officer upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such stock options.

(3) During February 2021 and 2022, the compensation committee awarded non-equity incentive plan compensation to certain executives and senior employees for the prior year's performance. See section entitled "Employment Agreements with Our Named Executive Officers" below for further details of non-equity incentive plan compensation that may be awarded under those agreements.

(4) Mr. Temperato was appointed as Chief Executive Officer effective April 30, 2020, upon closing of the RDD Merger.

(5) Mr. Sitar served as Chief Financial Officer until his separation from the Company, effective January 14, 2022.

Narrative Disclosure to Summary Compensation Table

The primary elements of compensation for our named executive officers consisted of base salary, equity-based compensation awards and other compensation such as discretionary bonuses and annual non-equity incentive bonuses. Our named executive officers are 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

Pursuant to their respective employment agreements, each named executive officer is eligible for an annual non-equity incentive award, based on goals established by the Board. In 2021 and 2020, the Board set goals related to various operational and financial objectives. For the year ended December 31, 2021, the Board determined that Mr. Temperato and Mr. Sitar will receive a bonus of $214,840 and $118,880, respectively, after determining that certain operational and financial objectives were met.

Equity Awards

The Company has two stock option plans in existence: the 2012 Omnibus Incentive Plan, as amended (the "Omnibus Plan"), and the Innovate 2015 Stock Incentive Plan (the "Private Innovate Plan"). We will no longer award options under the Private Innovate Plan. In addition, pursuant to the RDD Merger Agreement, we assumed previously issued option grant agreements awarded to RDD employees upon consummation of the RDD Merger on April 30, 2020. 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.

2021 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, 2021.

	Option Awards				
Name	Number of Securities Underlying Unexercised Options (#) Exercisable		Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date
John Temperato	246,743	(1)	—	$ 0.74	4/30/2025
	562,500	(2)	437,500	$ 0.70	4/30/2030
	109,913	(3)	200,432	$ 0.62	7/6/2030
	226,544	(3)	413,111	$ 1.07	11/27/2030
	—	(4)	650,000	$ 1.07	11/27/2030
	—	(5)	1,309,626	$ 1.81	2/4/2031
Edward J. Sitar [8]	350,000	(6)	—	$ 1.17	7/1/2029
	176,156	(7)	—	$ 0.60	4/24/2030
	70,313	(2)	54,688	$ 0.70	4/30/2030
	194,792	(3)	355,208	$ 0.62	7/6/2030
	—	(4)	225,000	$ 0.62	7/6/2030
	—	(5)	477,468	$ 1.81	2/4/2031

(1) This option was granted by RDD Pharma, Ltd. and was assumed by the Company pursuant to the RDD Merger Agreement upon consummation of the RDD Merger on April 30, 2020.

(2) This option was granted under the Omnibus Plan, and 25% of these options vested on April 30, 2020, with the remainder vesting monthly over the next 48 months.

(3) This option was granted under the Omnibus Plan, and 25% of these options will vest on July 6, 2021, with the remainder vesting monthly over the next 36 months.

(4) This option was granted under the Omnibus Plan, and began vesting upon satisfaction of certain performance criteria previously set by the Board. The Compensation Committee determined that the performance criteria was met and vesting began on January 1, 2021, with 25% vesting on January 1, 2022 and the remainder vesting over the next 36 months.

(5) This option was granted under the Omnibus Plan, and 25% of these options vest on February 4, 2022, with the remainder vesting monthly over the next 36 months.

(6) This option was granted under the Omnibus Plan, and 7.5% vested on December 31, 2019. The remainder of the options vesting was accelerated upon completion of the RDD Merger on April 30, 2020.

(7) This option was granted under the Omnibus Plan, and was fully vested on the date of grant, April 24, 2020.

(8) Mr. Sitar is serving as an independent consultant for the three months following the January 14, 2022 separation date. The material terms of Mr. Sitar's previously granted equity awards subject to time-based vesting remain unchanged and continue to vest during the consulting period. Following the end of the consulting period, the remaining unvested equity awards previously granted to Mr. Sitar subject to time-based vesting will be accelerated and become fully vested with the exercise period being extended to ten years from the issuance date.

Employment Agreements with Our Named Executive Officers

John Temperato

We entered into an executive employment agreement with Mr. Temperato, effective April 30, 2020, as amended on July 12, 2021,which included provisions with respect to, among other things, base salary. Pursuant to the executive employment agreement with Mr. Temperato, he receives an initial base salary of $450,000 per year, subject to review and adjustment by the Board from time to time. Effective January 1, 2021, Mr. Temperato's salary was increased to $537,100. Upon execution of the employment agreement, the Board approved an option grant to Mr. Temperato to purchase 1,000,000 shares of Common Stock, which vested 25% upon grant, with the remainder vesting in 48 equal month installments, provided that Mr. Temperato remains an employee of the Company as of each such vesting date. Mr. Temperato is eligible to receive an annual non-equity incentive cash award with a target amount of 40% of his base salary, as determined by the Board in its sole discretion (and pro-rated for 2020). Mr. Temperato is also eligible to participate in the Company's other employee benefit plans in effect from time to time on the same bases as are generally made available to other senior executive employees of the Company.

If the employment of Mr. Temperato is terminated by the Company without "Cause" or by Mr. Temperato for "Good Reason" (each as defined in the employment agreement, as amended), Mr. Temperato will be eligible to receive 12 months of his then-current salary, the prorated amount of his target year-end annual non-equity incentive award, and accelerated vesting of his unvested options and restricted stock unit awards that were scheduled to vest in the 12 months following termination. However, if such termination of employment occurs within 12 months of a "Change in Control" (as defined in the employment agreement, as amended), then Mr. Temperato will be eligible to receive 18 months of his then-current salary, the amount of his target year-end annual non-equity incentive award, and accelerated vesting of all of his unvested options and restricted stock unit awards. All separation benefits are subject to Mr. Temperato entering into and not revoking a separation agreement.

Effective November 27, 2020, the Board cancelled certain stock option awards to Mr. Temperato that were intended to be granted to Mr. Temperato on July 6, 2020 (collectively, the "Original Stock Options") under the 2012 Plan. The purpose of the cancellation was to correct an inadvertent error that occurred when the Company included a number of shares in the Original Stock Options that exceeded the previous annual individual award limit under the 2012 Plan of 1.5 million shares of common stock. The individual award limit was increased by the Board in November 2020 to 4 million shares of Company common stock. Following the increase of the individual award limit, and in lieu of the Original Stock Options that were granted in excess of the prior individual award limit, the Board granted Mr. Temperato the following new stock awards: 639,655 shares of common stock, subject to time-based vesting, and 650,000 shares of common stock, subject to performance-based vesting, each at an exercise price of $1.07. Additionally, the Board granted Mr. Temperato 203,667 shares of restricted stock, vesting on November 25, 2021, contingent upon his continued relationship with the Company, in order to compensate him for the lost value of the Original Stock Options due to the increased exercise price of the new options. The portion of the Original Stock Options relating to 310,345 shares of common stock that were not in excess of the prior individual award limit remain in effect. Prior option grants made to Mr. Temperato in April 2020 and June 2020 also remain in effect.

Edward J. Sitar

We entered into an executive employment agreement with Mr. Sitar effective July 1, 2019. Pursuant to the executive employment agreement with Mr. Sitar, Mr. Sitar received an annual base salary of $285,000, subject to periodic increase as the Company may determine. Effective January 1, 2021, Mr. Sitar's salary was increased to $371,500. Mr. Sitar's employment agreement provided that Mr. Sitar would receive an initial grant of options to purchase up to 350,000 shares of the Company's common stock, which award vest with respect to 7.5% of the shares on the six-month anniversary of July 1, 2019, 7.5% of the shares on the one-year anniversary of July 1, 2019, and the remainder of the shares in 36 equal monthly installments on the last day of each successive month thereafter. In addition to Mr. Sitar's initial equity award, Mr. Sitar was eligible to participate in (i) any equity compensation plan or similar program established by the Company and (ii) any bonus or similar incentive plans established by the Company that may be applicable to executives of the Company at Mr. Sitar's level, with participation in such bonus or similar incentive plans based on a target of 30% - 50% of Mr. Sitar's base salary. Mr. Sitar was also generally eligible to participate in employee benefit programs established by us from time to time that were applicable to our executives.

As of January 14, 2022, the Company entered into a separation and consulting agreement with Mr. Sitar, effective January 14, 2022 (the "Separation Date"). Pursuant to the separation and consulting agreement, Mr. Sitar is serving as an independent consultant for three months following the Separation Date (the "Consulting Period"). In connection with his separation, and following his non-revocation of a general release of claims, as provided in his employment agreement, Mr. Sitar will receive: (i) separation pay in an amount equal to 12 months of his regular base salary, minus applicable withholdings, paid in accordance with the Company's normal payroll practices; (ii) payment of his 2021 annual bonus, as determined by the Company's board of directors; and (iii) payment of his 2022 annual bonus prorated for his period of service prior to the Separation Date and during the Consulting Period. The material terms of Mr. Sitar's previously granted equity awards subject to time-based vesting remain unchanged and continue to vest during the Consulting Period. Following the end of the Consulting Period, the remaining unvested equity awards previously granted to Mr. Sitar subject to time-based vesting will be accelerated and become fully vested with an extension of the exercise period to ten years from the issuance date.

2021 Director Compensation

The following table provides compensation information regarding our non-employee directors for the year ended December 31, 2021.

Name	Fees Earned or Paid in Cash [1] ($)	Option Awards [2] ($)	Total ($)
Mark Sirgo, Pharm.D.	$ 93,750	$ 75,640	$ 169,390
Michael Constantino	$ 57,500	$ 75,640	$ 133,140
Lorin K. Johnson, Ph.D.	$ 58,750	$ 75,640	$ 134,390
Michael Rice [3]	$ 35,000	$ 153,354	$ 188,354
Samantha Ventimiglia [4]	$ 3,438	$ 117,601	$ 121,039
Nissim Darvish, M.D., Ph.D. [5]	$ 13,125	$ —	$ 13,125
Sandeep Laumas, M.D. [6]	$ 24,151	$ —	$ 24,151

(1) Fees earned or paid in cash reflect the non-employee director compensation earned or paid in cash during the year ended December 31, 2021.
(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 consolidated 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.
(3) Mr. Rice was appointed to the Board of Directors on February 12, 2021.
(4) Ms. Ventimiglia was appointed to the Board of Directors on October 1, 2021.
(5) Dr. Darvish resigned effective as of February 12, 2021.
(6) Dr. Laumas served as a director until the 2021 Annual Meeting of Stockholders on June 22, 2021.

The table below shows the aggregate number of option awards (vested and unvested) held as of December 31, 2021 by each of our non-employee directors who was serving as of that date.

Name	Aggregate Options Outstanding as of December 31, 2021
Mark Sirgo, Pharm.D.	486,743
Michael Constantino	240,000
Lorin K. Johnson, Ph.D.	616,492
Michael Rice	150,000
Samantha Ventimiglia	150,000

Non-Employee Director Compensation Policy

As of May 1, 2020, our non-employee directors receive the following annual retainers, to be paid quarterly:

Position	Retainer
Board member	$ 37,500
Chairman of the Board	35,000
Audit Committee Chair	15,000
Audit Committee member	7,500
Compensation Committee Chair	10,000
Compensation Committee member	7,500
Nominating and Corporate Governance Chair	7,500
Nominating and Corporate Governance member	3,750

Under the policy, 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 150,000 shares of our common stock. The initial equity awards will vest monthly over a period of three years, subject to continued service on our Board. In addition, each non-employee director who serves on the Board as of the date of any Annual Meeting will automatically be granted an option on the date of such Annual Meeting, with the number of options and vesting period to be determined by the Compensation Committee.

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 bylaws.

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 18, 2022 (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 18, 2022, 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 9 Meters Biopharma, Inc., 8480 Honeycutt Road, Suite 120, Raleigh, NC 27615.

Name and Address of Beneficial Owner	Shares Beneficially Owned	Percent of Outstanding[1]
Principal Stockholders:		
OrbiMed Advisors, LLC [2]	15,384,418	5.9 %
Adage Capital Management, L.P. [3]	15,000,000	5.8 %
BlackRock, Inc. [4]	14,164,801	5.5 %
Directors and Named Executive Officers:		
John Temperato [5]	3,326,214	1.3 %
Edward J. Sitar [6]	2,165,762	*
Bethany Sensenig	—	*
Mark Sirgo, Pharm.D. [7]	1,884,667	*
Lorin K. Johnson, Ph.D. [8]	662,759	*
Michael Constantino [9]	161,176	*
Michael Rice [10]	58,333	*
Samantha Ventimiglia [11]	29,167	*
All directors and executive officers as a group (7 persons) [12]	6,129,915	2.3 %

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

(1) The percentage of beneficial ownership is based on 258,235,418 shares of common stock outstanding as of March 18, 2022.

(2) Based solely on Company records and a Schedule 13D/A filed with the SEC on June 28, 2021 by OrbiMed Israel BioFund GP Limited Partnership and OrbiMed Israel GP Ltd. Consists of (i) 10,697,918 shares of common stock and (ii) warrants to purchase up to 4,686,500 shares of common stock. The managing member of Orbimed Advisors, LLC is a former director of the Company, Nissim Darvish. The address for Orbimed Advisors, LLC is 89 Medinat Ha Yehudim St. Israel 4676672 P.O. Box.

(3) Based solely on a Schedule 13G/A filed with the SEC on February 10, 2022 by Adage Capital Partners, L.P. Consists of 15,000,000 shares of common stock held directly by Adage Capital Partners, L.P. The address for Adage Capital Partners, L.P. is 200 Clarendon Street, 52nd Floor, Boston, Massachusetts 02116.

(4) Based solely on a Schedule 13G filed with the SEC on February 4, 2022 by BlackRock, Inc. BlackRock, Inc. reported in its Schedule 13G/A that it has sole voting power over 14,087,913 shares, sole dispositive power over 14,164,801 shares and no shared voting power or shared dispositive power over any shares. The address for BlackRock, Inc. is 55 East 52nd Street, New York, NY 10055.

(5) Consists of (i) 1,152,522 shares of common stock held by Mr. Temperato, (ii) options to purchase 1,902,292 shares of common stock held by Mr. Temperato that are exercisable within 60 days of March 18, 2022, and (iii) warrants to purchase up to 271,400 shares of common stock.

(6) Consists of (i) 194,338 shares of common stock held by Mr. Sitar, (ii) options to purchase 1,903,624 shares of common stock held by Mr. Sitar that are exercisable within 60 days of March 18, 2022, and (iii) warrants to purchase up to 67,800 shares of common stock.

(7) Consists of (i) 1,242,595 shares of common stock held by Dr. Sirgo, (ii) 21,485 shares of common stock held by Dr. Sirgo's spouse; (iii) options to purchase 366,187 shares of common stock exercisable within 60 days of March 18, 2022, and (iv) warrants to purchase up to 254,400 shares of common stock.

(8) Consists of (i) 84,800 shares of common stock held by Dr. Johnson, (ii) options to purchase 493,159 shares of common stock that are exercisable within 60 days of March 18, 2022, and (iii) warrants to purchase up to 84,800 shares of common stock.

(9) Consists of (i) 44,508.74 shares of common stock held by Mr. Constantino and (ii) options to purchase 116,667 shares of common stock that are exercisable within 60 days of March 18, 2022.

(10) Consists of options to purchase 58,333 shares of common stock that are exercisable within 60 days of March 18, 2022.

(11) Consists of options to purchase 29,167 shares of common stock that are exercisable within 60 days of March 18, 2022.

(12) Consists of (i) 2,553,510 shares of common stock, (ii) options to purchase 2,965,805 held by the Company's current directors and executive officers that are exercisable within 60 days of March 18, 2022, and (iii) warrants to purchase up to 610,600 shares of common stock.

Equity Compensation Plan Information

The following table provides aggregate information as of December 31, 2021, 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]	19,908,960	$ 1.32	5,478,787
Equity compensation plans not approved by security holders [2]	985,807	$ 0.63	—
Total	20,894,767	$ 1.29	5,478,787

(1) Consists of (i) 5,300,518 shares of common stock issuable upon exercise of outstanding options under the Private Innovate Plan and (ii) 14,608,442 shares of common stock issuable upon exercise of outstanding options under the Omnibus Plan. As of December 31, 2021, there were 5,478,787 shares remaining for future issuance under the Omnibus Plan. 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 31 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, 2022, the number of shares of common stock available under the Omnibus Plan automatically increased by 12,911,771 shares pursuant to the Evergreen Provision.

(2) Pursuant to the RDD Merger Agreement, upon consummation of the RDD Merger on April 30, 2020, the Company assumed outstanding option grant agreements that were awarded to RDD employees. There were 985,807 assumed RDD options outstanding as of December 31, 2021, with a weighted-average exercise price of $0.63 per share. See "Note 9—Share-Based Compensation" to the accompanying consolidated financial statements included in this Annual Report on Form 10-K for further discussion of the assumed RDD options.

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, 2020, 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 the lesser of (a) $120,000 or (b) 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, 2020 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:

On May 4, 2020, we closed the RDD Merger Financing and sold an aggregate of (i) 382,779 shares of Series A Preferred Stock, par value $0.0001 per share, which converted into 38,277,900 shares of common stock on June 30, 2020, upon receipt of approval by our stockholders, and (ii) Preferred Warrants to purchase up to 382,779 shares of Series A Preferred Stock, which following the Automatic Conversion became exercisable for 38,277,900 shares of common stock. Our Chief Executive Officer, Chief Financial Officer and members of our Board (collectively referred to as the "9 Meters Purchasers"), purchased an aggregate of 7,507,300 shares of common stock in the offering at the public offering price and on the same terms as the other purchasers in the offering. The underwriters received the same underwriting discount on the shares purchased by the 9 Meters Purchasers. The aggregate purchase price of the common stock units issued to the 9 Meters Purchasers was approximately $4.4 million.

Pursuant to the underwriting agreement in connection with the December 2020 Offering, we issued an aggregate of 53,076,924 shares of common stock at a price of $0.65 per share. Of the shares issued in the December 2020 Offering, our Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors purchased an aggregate of 446,153 shares of common stock in this offering at the public offering price and on the same terms as the other purchasers in the offering. The underwriters received the same underwriting discount on the shares purchased by our Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors. The aggregate purchase price of the common stock shares issued to our Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors was $290,000.

Pursuant to the underwriting agreement in connection with the April 2021 Offering, the Company issued an aggregate of 34,500,000 shares of common stock at a price of $1.00 per share. Of the shares issued in the April 2021 Offering, the Company's Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors purchased an aggregate of 450,000 shares at the public offering price and on the same terms as the other purchasers in the April 2021 Offering. The underwriters received the same underwriting discount on the shares purchased by the Company's Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors as the other shares sold in the offering. The aggregate purchase price of the common stock shares issued to the Company's Chief Executive Officer, Chief Financial Officer and Chairman of the Board was $450,000.

Agreement with LifeSci Advisors

Michael Rice, a member of our Board since March 2021, is a Founding Partner of LifeSci Advisors, LLC and LifeSci Communications, LLC. Prior to his becoming a director, on April 1, 2020 we entered into a master services agreement with both LifeSci Advisors, LLC and LifeSci Communications, LLC, to provide investor relations and public relations services, respectively. During the year ended December 31, 2021, we incurred expenses of approximately $0.3 million with LifeSci Advisors, LLC and $0.3 million with LifeSci Communications, LLC. During the year ended December 31, 2020, we incurred expenses of approximately $0.1 million with LifeSci Advisors, LLC and approximately $0.1 million in expenses with LifeSci Communications, LLC.

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 our company's Board, that director does not have a relationship that would interfere with such director'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 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.

Our 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 background, employment and affiliations, including family relationships, our Board has determined that each of Michael Constantino, Lorin Johnson, Ph.D., Michael Rice, Mark Sirgo, Pharm.D., and Samantha Ventimiglia, 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.

Our Board also determined that each of Michael Constantino (Chair), Mark Sirgo, Pharm.D., and Lorin Johnson, Ph.D., 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.

Our Board has determined that Lorin Johnson, Ph.D. (Chair), Mark Sirgo, Pharm.D. and Michael Rice, the three current members of our compensation committee, and Michael Rice (Chair), Michael Constantino, Lorin Johnson, Ph.D., Mark Sirgo, Pharm.D. and Samantha Ventimiglia, the five members of our nominating and corporate governance committee, are 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, 2021 and 2020.

	Fiscal Year Ended	
	2021	2020
	(in thousands)	
Audit Fees [1]	$ 253	$ 349
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$ 253	$ 349

(1) Audit fees consist of fees billed for the professional services rendered to the Company for the audit of the Company's annual consolidated financial statements for the years ended December 31, 2021 and 2020, 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 on Form 10-K.

(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, 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
2.1.1	*	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
2.2	*	Agreement and Plan of Merger, dated April 30, 2020, among Innovate Biopharmaceuticals, Inc., Naia Merger Sub, Inc., Second Naia Merger Sub LLC, and Naia Rare Diseases, Inc.		8-K	2.1	May 4, 2020
2.3	*	Asset Purchase Agreement between 9 Meters Biopharma, Inc. and Lobesity, LLC, dated July 19, 2021.		10-Q	2.1	November 15, 2021
3.1		Amended and Restated Certificate of Incorporation of the Company, as amended.		10-Q	3.1	August 12, 2021
3.1.1		Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Company.		8-K	3.1	May 4, 2020
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.		10-K	4.2	March 20, 2020
4.3		Form of Warrant.		8-K	4.1	February 2, 2018
4.4		Form of Common Stock Purchase Warrant.		8-K	4.1	May 1, 2019
4.5		Form of Placement Agent Warrant.		8-K	4.2	May 1, 2019
4.6		Form of Series A Convertible Preferred Stock Warrant.		8-K	4.1	May 4, 2020
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 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

EXHIBIT NO.		DESCRIPTION	FILED HEREWITH	INCORPORATED BY REFERENCE		
				FORM	EXHIBIT	FILING DATE
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	June 30, 2020
10.7.1	#	Amendment to the 2012 Omnibus Incentive Plan, dated November 27, 2020.		8-K	10.1	November 27, 2020
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
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	*	Securities Purchase Agreement, dated April 29, 2020, between Innovate Biopharmaceuticals, Inc. and the investors named therein.		8-K	10.1	May 4, 2020
10.16	*	Registration Rights Agreement, dated April 29, 2020, between Innovate Biopharmaceuticals, Inc. and the investors named therein.		8-K	10.2	May 4, 2020
10.17	#	Employment Agreement dated April 30, 2020, between Innovate Biopharmaceuticals, Inc. and John Temperato.		8-K	10.6	May 4, 2020
10.17.1	#	First Amendment dated July 12, 2021, to Employment Agreement dated April 30, 2020, between 9 Meters Biopharma, Inc. (formerly Innovate Biopharmaceuticals, Inc.) and John Temperato.	X			
10.18	*	Amended and Restated Exclusive License Agreement, dated February 10, 2020, between Cedars-Sinai Medical Center and Naia Rare Diseases, Inc.		10-Q	10.7	August 13, 2020
10.19	*	Side Letter, dated May 1, 2020, between Amunix Pharmaceuticals, Inc. and Naia Rare Diseases, Inc.		10-Q	10.8	August 13, 2020
10.20	*	Second Amended and Restated License Agreement, dated May 1, 2020, between Amunix Pharmaceuticals, Inc. and Naia Rare Diseases, Inc.		10-Q	10.9	August 13, 2020
10.21	*	Amended and Restated License Agreement, dated May 1, 2020, between Amunix Pharmaceuticals, Inc. and Naia Rare Diseases, Inc.		10-Q	10.10	August 13, 2020
10.22	#	Form of RDD Pharma, Ltd. Notice of Option Grant.		10-Q	10.11	August 13, 2020
21.1		List of Subsidiaries of Registrant.		10-K	21.1	March 22, 2021
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			

EXHIBIT NO.	DESCRIPTION	FILED HEREWITH	INCORPORATED BY REFERENCE		
			FORM	EXHIBIT	FILING DATE
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	Inline XBRL Instance Document.	X			
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X			
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X			
101.DEF	Inline XBRL Taxonomy Extension Definition Document.	X			
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X			
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X			
104.0	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	X			

† 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.

Management contract or other compensatory plan.

* Certain confidential portions and/or the schedules and attachments to this exhibit have been omitted from this filing pursuant to Item 601(a)(5), 601(b)(2), or 601(b)(10), as applicable, of Regulation S-K. The Company will furnish copies of the unredacted exhibit to the SEC upon request.

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 23, 2022

9 Meters Biopharma, Inc.

By: /s/ John Temperato
Name: John Temperato
Title: Chief Executive Officer

Signature	Title	Date
/s/ John Temperato John Temperato	President & Chief Executive Officer and Director (Principal Executive Officer)	March 23, 2022
/s/ Bethany Sensenig Bethany Sensenig	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 23, 2022
/s/ Lorin K. Johnson Lorin K. Johnson, Ph.D.	Director	March 23, 2022
/s/ Mark Sirgo, Pharm.D. Mark Sirgo, Pharm.D.	Director	March 23, 2022
/s/ Michael T. Constantino Michael T. Constantino	Director	March 23, 2022
/s/ Michael Rice Michael Rice	Director	March 23, 2022
/s/ Samantha Ventimiglia Samantha Ventimiglia	Director	March 23, 2022

9 METERS BIOPHARMA, INC.

TABLE OF CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and
Stockholders of **9 Meters Biopharma, Inc.**

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of **9 Meters Biopharma, Inc.** (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2021, 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, 2021 and 2020, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2021, 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 expects to continue to incur negative cash flows from operations with no revenue source, and is therefore dependent on cash on hand and 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 also described in Note 2. 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 might 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 2015.

San Diego, California
March 23, 2022

9 METERS BIOPHARMA, INC.
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 46,993,285	$ 37,851,388
Restricted deposit	—	75,000
Prepaid expenses and other current assets	2,991,948	1,000,587
Total current assets	49,985,233	38,926,975
Property and equipment, net	16,094	11,191
Right-of-use asset	166,618	214,767
Other assets	5,580	5,580
Total assets	$ 50,173,525	$ 39,158,513
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,434,452	$ 1,487,948
Accrued expenses	5,967,822	5,290,181
Convertible note payable, net	—	14,216
Derivative liability	—	7,000
Accrued interest	—	488
Lease liability, current portion	54,796	48,629
Total current liabilities	8,457,070	6,848,462
Lease liability, net of current portion	113,142	167,938
Total liabilities	8,570,212	7,016,400
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock $0.0001 par value as of December 31, 2021 and 2020, 10,000,000 shares authorized as of December 31, 2021 and 2020; 0 shares issued and outstanding as of December 31, 2021 and 2020	—	—
Common stock $0.0001 par value as of December 31, 2021 and 2020, 550,000,000 and 350,000,000 shares authorized as of December 31, 2021 and 2020, respectively, 258,235,418 and 204,629,064 shares issued and outstanding as of December 31, 2021 and 2020, respectively	25,824	20,463
Additional paid-in capital	210,418,156	164,182,917
Accumulated deficit	(168,840,667)	(132,061,267)
Total stockholders' equity	41,603,313	32,142,113
Total liabilities and stockholders' equity	$ 50,173,525	$ 39,158,513

See accompanying notes to these consolidated financial statements.

9 METERS BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 21,995,291	$ 10,933,023
Acquired in-process research and development	5,103,753	32,266,893
General and administrative	9,662,875	10,519,955
Warrant inducement expense	—	7,157,887
Total operating expenses	36,761,919	60,877,758
Loss from operations	(36,761,919)	(60,877,758)
Other income (expense):		
Interest income	22,707	18,992
Interest expense	(47,188)	(4,046,223)
Change in fair value of derivative liability	7,000	771,000
Change in fair value of warrant liabilities	—	2,637,500
Total other income (expense), net	(17,481)	(618,731)
Loss before income taxes	(36,779,400)	(61,496,489)
Income tax benefit	—	—
Net loss	$ (36,779,400)	$ (61,496,489)
Net loss per common share, basic and diluted	$ (0.15)	$ (0.58)
Weighted-average common shares, basic and diluted	243,108,526	105,642,203

See accompanying notes to these consolidated financial statements.

9 METERS BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Series A Preferred Shares	Series A Preferred Amount	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance as of December 31, 2019	—	$ —	39,477,667	$ 3,948	$ 60,946,816	$ (70,564,778)	$ (9,614,014)
Issuance of common stock	—	—	56,611,767	5,660	37,163,320	—	37,168,980
Issuance of common stock (RDD & Naia mergers)	—	—	42,695,948	4,270	28,749,756	—	28,754,026
Issuance of preferred stock and warrants (FN-1)	382,779	38	—	—	22,560,956	—	22,560,994
Conversion of preferred stock to common stock	(382,779)	(38)	38,277,900	3,828	(3,790)	—	—
Warrant exchange	—	—	1,847,309	185	690,654	—	690,839
Vesting of RSUs	—	—	415,948	42	(42)	—	—
Share-based compensation	—	—	—	—	4,723,000	—	4,723,000
Stock issuance costs	—	—	—	—	(6,483,998)	—	(6,483,998)
Exercise of warrants	—	—	14,452,418	1,445	2,527,203	—	2,528,648
Inducement expense	—	—	—	—	6,467,048	—	6,467,048
Conversion of convertible debt and accrued interest	—	—	10,850,107	1,085	4,641,922	—	4,643,007
Beneficial conversion feature	—	—	—	—	2,200,072	—	2,200,072
Net loss	—	—	—	—	—	(61,496,489)	(61,496,489)
Balance as of December 31, 2020	—	$ —	204,629,064	$ 20,463	$ 164,182,917	$(132,061,267)	$ 32,142,113
Issuance of common stock	—	—	37,017,211	3,702	37,214,886	—	37,218,588
Vesting of RSUs	—	—	203,667	20	(20)	—	—
Share-based compensation	—	—	—	—	2,413,000	—	2,413,000
Stock issuance costs	—	—	—	—	(2,901,123)	—	(2,901,123)
Exercise of warrants	—	—	15,546,851	1,555	9,161,619	—	9,163,174
Exercise of stock options	—	—	838,625	84	346,877	—	346,961
Net loss	—	—	—	—	—	(36,779,400)	(36,779,400)
Balance as of December 31, 2021	—	$ —	258,235,418	$ 25,824	$ 210,418,156	$(168,840,667)	$ 41,603,313

See accompanying notes to these consolidated financial statements.

9 METERS BIOPHARMA, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year Ended December 31,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (36,779,400)	$ (61,496,489)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	2,413,000	4,723,000
Accrued interest on convertible notes	—	307,372
Amortization of debt discount	43,983	1,519,668
Depreciation	7,573	18,491
Loss on disposal and write-offs of property and equipment	—	39,198
Beneficial conversion feature	—	2,200,072
Acquired in-process research and development	2,610,588	28,754,026
Change in fair value of derivative liability	(7,000)	(771,000)
Change in fair value of warrant liabilities	—	(2,637,500)
Warrant inducement expense	—	7,157,887
Changes in operating assets and liabilities, net of acquisitions:		
Prepaid expenses and other assets	(1,991,361)	(445,535)
Accounts payable	1,054,504	(2,465,074)
Accrued expenses	3,170,326	3,685,610
Accrued interest	(488)	488
Net cash used in operating activities	(29,478,275)	(19,409,786)
Cash flows from investing activities		
Purchase of property and equipment	(12,476)	(2,543)
Purchase of in-process research and development, net of assets acquired	(2,493,165)	(3,184,454)
Maturity of restricted deposit	75,000	—
Net cash used in investing activities	(2,430,641)	(3,186,997)
Cash flows from financing activities		
Borrowings from convertible notes	—	2,500,000
Payments of debt issuance costs	—	(23,000)
Payments of convertible notes	(58,199)	(2,461,472)
Proceeds from issuance of common stock and warrants	34,500,000	37,147,681
Proceeds from issuance of preferred stock and warrants	—	22,560,994
Proceeds from exercise of stock options	346,961	—
Proceeds from exercise of warrants	9,163,174	2,528,648
Payment of offering costs	(2,901,123)	(6,397,612)
Net cash provided by financing activities	41,050,813	55,855,239
Net increase in cash and cash equivalents	9,141,897	33,258,456
Cash and cash equivalents as of beginning of year	37,851,388	4,592,932
Cash and cash equivalents as of end of year	$ 46,993,285	$ 37,851,388
Supplemental disclosure of cash flow information		
Cash paid during the year for interest	$ 569	$ 62,912
Supplemental disclosure of non-cash financing activities		
Conversion of convertible notes and accrued interest to common stock	$ —	$ 4,643,007
Non-cash issuance of common stock with acquisitions and merger	$ 2,610,588	$ 28,754,026
Issuance of common stock for settlement of accounts payable	$ 108,000	$ —
Non-cash addition of derivative liability	$ —	$ 370,000
Non-cash addition of deferred offering costs	$ —	$ 86,386

See accompanying notes to these consolidated financial statements.

NOTE 1: SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Business Description

9 Meters Biopharma, Inc. (the "Company") is a clinical-stage company pioneering novel treatments for people with rare digestive diseases, gastrointestinal conditions with unmet needs, and debilitating disorders in which the biology of the gut is a contributing factor. The Company's pipeline includes drug candidates vurolenatide, a proprietary long-acting GLP-1 agonist for short bowel syndrome ("SBS"), an orphan designated disease, larazotide, a Phase 3 tight junction regulator being evaluated for celiac disease ("CeD"), and a robust pipeline of early-stage candidates for undisclosed rare diseases and/or unmet needs.

On April 30, 2020, the Company completed its merger with privately-held RDD Pharma, Ltd., an Israel corporation ("RDD") (the "RDD Merger") and changed its name from Innovate Biopharmaceuticals, Inc. to 9 Meters Biopharma, Inc.

Basis of Presentation

The accompanying consolidated 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.

The accompanying consolidated financial statements and related notes reflect the historical results of Innovate Biopharmaceuticals, Inc. prior to the RDD Merger and of the combined company following the RDD Merger.

Basis of Consolidation

The accompanying consolidated financial statements reflect the operations of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Shelf Registration Filing

On October 2, 2020, the Company filed a shelf registration statement that was declared effective on October 9, 2020 (the "Current Registration Statement"). Pursuant to the Current Registration Statement, the Company may from time to time offer, issue and sell in one or more offerings of various types of securities up to an aggregate dollar amount of $200 million.

On July 22, 2020, the Company filed a prospectus supplement and associated sales agreement related to an "at-the-market" offering ("ATM") pursuant to which the Company may sell, from time to time, common stock with an aggregate offering price of up to $40 million through Truist Securities, Inc. (previously SunTrust Robinson Humphrey), or Truist, as sales agent, for general corporate purposes (the "Sales Agreement"). In October 2020, the Company entered into an amendment to the Sales Agreement to reflect the termination of the Prior Registration Statement and effectiveness of the Current Registration Statement. During the year ended December 31, 2021, the Company did not sell any shares under the Sales Agreement. During the year ended December 31, 2020, the Company sold 3,496,045 shares of the Company's common stock pursuant to the Sales Agreement for net proceeds of approximately $2.6 million.

Warrant Exchange

Pursuant to a securities purchase agreement entered into with certain institutional and accredited investors on April 29, 2019, the Company issued warrants with an initial exercise price of $2.13 per share and a term of five-and-a-half years (the "April Warrants"). In addition, the Company issued placement agent warrants on April 29, 2019 with an initial exercise price of $2.53 per share and had a term of 5 years (the "Placement Agent Warrants"). On December 19, 2019, the Company and each of the purchasers of the April Warrants and the Placement Agent Warrants (collectively, the "Exchange Warrants") entered into separate 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. During the year ended December 31, 2020, Exchange Warrants to purchase an aggregate of 1,539,424 warrants were exchanged for 1,847,309 shares of the Company's common stock. All of the April Warrants and Placement Agent Warrants were exchanged as of December 31, 2020.

Offer to Amend and Exercise

On February 12, 2020, the Company offered to amend certain outstanding warrants in the Offer to Amend and Exercise. The warrants amended included the short-term warrants issued in 2019 that were classified as warrant liabilities (the "Short-Term Warrants"), as well as warrants classified as equity issued in 2018 and the outstanding long-term warrants issued in 2019 that were classified as warrant liabilities (collectively, the "Long-Term Warrants"). On April 29, 2020, Short-Term Warrants and Long-Term Warrants to purchase an aggregate of 12,230,418 shares of common stock were tendered, amended and exercised for $0.10 per share for aggregate gross proceeds of approximately $1.2 million. All of the warrants classified as warrant liabilities were fully exercised at an exercise price of $0.10 per share and as such, there were no warrant liabilities outstanding as of December 31, 2021 or 2020.

RDD Merger Financing

On April 29, 2020, the Company entered into a securities purchase agreement with various accredited investors pursuant to which the Company agreed to issue and sell to the investors units ("Units") consisting of (i) one share of Series A Convertible Preferred Stock (the "Series A Preferred Stock") and (ii) one five-year warrant (the "Preferred Warrants") to purchase one share of Series A Preferred Stock (the "RDD Merger Financing"). On May 4, 2020, the Company closed the RDD Merger Financing and the Company sold an aggregate of (i) 382,779 shares of Series A Preferred Stock, par value $0.0001 per share, which converted into 38,277,900 shares of common stock on June 30, 2020, upon receipt of approval by the Company's stockholders (the "Automatic Conversion"), and (ii) Preferred Warrants to purchase up to 382,779 shares of Series A Preferred Stock, which following the Automatic Conversion became exercisable for 38,277,900 shares of common stock. The exercise price of the Preferred Warrants was $58.94 per share of Series A Preferred Stock, and following the Automatic Conversion, became $0.5894 per share of common stock, subject to adjustments as provided under the terms of the Preferred Warrants. In addition, broker warrants covering 8,112 Units and broker warrants covering 10,899 shares of Series A Preferred Stock, which following the Automatic Conversion became exercisable for an aggregate of 2,712,300 shares of common stock, were issued in connection with the RDD Merger Financing. Gross proceeds from the RDD Merger Financing were approximately $22.6 million with net proceeds of approximately $19.2 million after deducting commissions and estimated offering costs. See Note 3—Merger & Acquisition for additional details.

December 2020 Offering

On December 11, 2020, the Company entered into an underwriting agreement (the "December Underwriting Agreement") with William Blair & Company, L.L.C. and Truist, as representatives of the several underwriters named therein, in connection with the public offering of 46,153,847 shares of the Company's common stock at a price of $0.65 per share, less underwriting discounts and commissions (the "December 2020 Offering"). Pursuant to the terms of the December Underwriting Agreement, the Company granted the underwriters a 30-day option to purchase up to an additional 6,923,077 shares of common stock at the same price, which the underwriters exercised in full on December 14, 2020. On December 15, 2020, upon closing of the December 2020 Offering, the Company received net proceeds of approximately $32.0 million after deducting underwriting discounts and commissions and offering expenses. The shares issued in the December 2020 Offering were registered and sold under the Current Registration Statement.

Of the shares of common stock issued in the December 2020 Offering, the Company's Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors purchased an aggregate of 446,153 shares at the public offering price and on the same terms as the other purchasers in the offering. The underwriters received the same underwriting discount on the shares purchased by the Company's Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors as the other shares issued in the December 2020 Offering.

April 2021 Offering

On March 30, 2021, the Company entered into an underwriting agreement (the "March Underwriting Agreement") with Citigroup Global Markets, Inc., William Blair & Company, L.L.C. and Truist, as representatives of the several underwriters named therein, in connection with the public offering of 30,000,000 shares of the Company's common stock at a price of $1.00 per share, less underwriting discounts and commissions (the "April 2021 Offering"). Pursuant to the terms of the March Underwriting Agreement, the Company granted the underwriters a 30-day option to purchase up to an additional 4,500,000 shares of common stock at the same price, which the underwriters exercised in full on March 31, 2021. On April 5, 2021, upon closing of the April 2021 Offering, the Company received net proceeds of approximately $31.5 million after

deducting underwriting discounts and commissions and offering expenses. The shares issued in the April 2021 Offering were registered and sold under the Current Registration Statement.

Of the shares of common stock issued in the April 2021 Offering, the Company's Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors purchased an aggregate of 450,000 shares at the public offering price and on the same terms as the other purchasers in the offering. The underwriters received the same underwriting discount on the shares purchased by the Company's Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors as the other shares issued in the April 2021 Offering.

Business Risks

The Company faces risks, including those associated with biopharmaceutical companies whose products are in various stages of development. These risks include, among others, risks related to the potential effects of the ongoing coronavirus outbreak and related mitigation efforts on the Company's clinical, financial and operational activities, 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.

The outbreak of COVID-19 began in December 2019 and on March 11, 2020, the World Health Organization declared the outbreak a pandemic. The COVID-19 pandemic and its resurgences 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 (the "FDA") and other health authorities, which could result in delays of reviews and approvals, including with respect to the Company's product candidates. The COVID-19 pandemic has led to slower enrollment in the Company's Phase 3 registration trial for larazotide and could continue to impact enrollment directly or indirectly for the next several months and possibly longer. 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 larazotide or the Company's other product candidates. New and potentially more contagious variants, such as the Omicron variant, could further affect the impact that the COVID-19 pandemic has on the Company's operations. The impact of the COVID-19 pandemic on the global financial markets may reduce the Company's ability to access capital in the future, which could negatively impact the Company's long-term liquidity. The Company's assessment of the 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 the Company relies.

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. The Company considered the impact of the COVID-19 pandemic on its estimates and assumptions, and concluded there was not a material impact to its consolidated financial statements as of and for the year ended December 31, 2021. 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 maintained a certificate of deposit ("CD") with a bank, which matured on October 17, 2021 and paid interest at a rate of 0.02% per annum. The CD served as collateral for the Company's credit cards with the bank through July 2021.

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,	
	2021	**2020**
Accrued compensation and benefits	$ 1,633,295	$ 1,111,028
Accrued clinical expenses	4,228,048	4,042,277
Other accrued expenses	106,479	136,876
Total	$ 5,967,822	$ 5,290,181

Derivative Liability

The Company accounts for derivative instruments in accordance with 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 consolidated balance sheet at fair value. The Company's derivative financial instruments consisted of embedded options in the Company's convertible notes. The embedded derivatives included provisions that provided 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.

Classification of Warrants

The Company accounts for warrants in accordance with ASC 480—*Distinguishing Liabilities from Equity* and ASC 815—*Derivatives and Hedging*, to determine whether the warrants should be classified as equity or liability. Warrants that are freestanding financial instruments that contain net settlement options and may require the Company to settle these warrants in cash under certain circumstances are classified as warrant liabilities. Warrant liabilities are initially recorded at fair value on

the date of issuance and are subsequently re-measured to fair value at each balance sheet date until the warrant liabilities are exercised or settled. Changes in the fair value of warrant liabilities are recognized as a non-cash component of other income and expense in the accompanying consolidated statements of operations and comprehensive loss. The Company had no warrant liabilities as of December 31, 2021 or 2020.

On May 4, 2020, the Company issued the Preferred Warrants, which are freestanding financial instruments that give the warrant holder the right but not the obligation to purchase the equity security at the warrant exercise price. The Company is not required to settle these warrants in cash and as such, the Company has classified these warrants as equity on the accompanying consolidated balance sheets.

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.

Acquired In-process Research and Development

The Company has acquired, and may in the future acquire, rights to develop and commercialize new drug candidates and/or other in-process research and development assets. The up-front acquisition payments, as well as future milestone payments that are deemed probable to achieve and do not meet the definition of a derivative, are expensed as acquired in-process research and development provided that the drug has not achieved regulatory approval for marketing, and, absent obtaining such approval, have no alternative future use.

Share-Based Compensation

The Company recognizes share-based compensation expense for grants of stock options 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 with time-based vesting. For awards with performance conditions, compensation cost is recognized from the time achievement of the performance criteria is probable over the expected term.

Share-based compensation expense 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 with service conditions 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 Accounting Standards Update ("ASU") 2018-07, the Company has elected to use the contractual life of the option as the expected term for non-employee options. The expected term for performance options is the longer of the explicit or implicit service period.

Periodically, the Board of Directors of the Company (the "Board") may approve the grant of restricted stock units ("RSUs") pursuant to the Company's 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 consolidated financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the consolidated 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 consolidated 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 Unsecured Convertible Note and the Additional 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 was 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 Unsecured Convertible Note and the Additional Note on their respective dates of issuance as of March 8, 2019 and January 10, 2020, respectively, and December 31, 2020.

	Derivative Liability		
	December 31, 2020	January 10, 2020	March 8, 2019
Discount rate	21.8 %	21.6 %	29.3 %
Expected stock price volatility	83.3 %	103.9 %	101.1 %
Risk-free interest rate	0.1 %	1.6 %	2.5 %
Expected term	1.0 Year	2.0 Years	2.0 Years
Price of the underlying common stock	$ 0.86	$ 0.65	$ 1.99

The fair values of the warrants at their respective dates of issuance 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 Long-Term Warrants could 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 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. During the year ended December 31, 2020 an aggregate of 1,539,424 warrants were exchanged for 1,847,309 shares of the Company's common stock.

In addition, the Company amended the Short-Term Warrants and Long-Term Warrants in the Offer to Amend and Exercise on February 12, 2020. Management 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 immediately prior to the Offer to Amend and Exercise, for financial reporting purposes, through the use of the Black-Scholes model. Subsequent to the Offer to Amend and Exercise, the Company determined the fair value of the Short-Term Warrants and Long-Term Warrants using the reduced exercise price of $0.10 as of April 28, 2020. 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 Company recognized a gain in fair value of the Short-Term Warrants and Long-Term Warrants of approximately $2.6 million during the year ended December 31, 2020. All of the Short-Term Warrants and Long-Term Warrants were exercised in the Offer to Amend and Exercise, which closed on April 29, 2020. During the year ended December 31, 2020, the Company recognized inducement expense of approximately $7.2 million. The warrant inducement expense represents the accounting fair value of consideration issued to induce conversion of the Exchange Warrants and exercise of the warrants in the Offer to Amend and Exercise.

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	January 6, 2020
Conversion price	$2.13 - $2.53	$ 2.13
Expected stock price volatility	84.1 %	87.3 %
Risk-free interest rate	2.2 %	1.7 %
Expected term	5 - 5.5 years	4.9 years
Price of the underlying common stock	$ 1.54	$ 0.58

The table below summarizes the range of valuation inputs into the Black-Scholes model for the warrant liabilities as of February 11, 2020, immediately prior to the reduction in exercise price pursuant to the Offer to Amend and Exercise.

	Short-Term Warrants	Long-Term Warrants
	February 11, 2020	
Conversion price	$ 4.00	$2.13 - $2.56
Expected stock price volatility	97.1 %	87.9% - 89.2%
Risk-free interest rate	1.6 %	1.7 %
Expected term	7 months	4 years, 2 months
Price of the underlying common stock	$ 0.79	$ 0.79

The following table summarizes the fair value hierarchy of financial liabilities measured at fair value as of December 31, 2020. There were no financial liabilities measured at fair value as of December 31, 2021.

	December 31, 2020			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Derivative liability	$ —	$ —	$ 7,000	$ 7,000
Warrant liabilities	—	—	—	—
Total liabilities at fair value	$ —	$ —	$ 7,000	$ 7,000

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,	
	2021	2020
Beginning balance	$ 7,000	$ 3,045,500
Issuance of derivative liability (the Additional Note)	—	370,000
Exchange of the April Warrants and Placement Agent Warrants	—	(380,600)
Change in fair value of warrant liabilities	—	(1,198,200)
Change in fair value of derivative liability	(7,000)	(771,000)
Exercise of the Short-Term Warrants and Long-Term Warrants	—	(1,058,700)
Ending balance	$ —	$ 7,000
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	$ —	$ 771,000

The cumulative unrealized gain relating to the change in fair value of the derivative liability and warrant liabilities of $1,969,200, the gain on exercise of the warrants in the Offer to Amend and Exercise of $1,058,700 and the gain on exchange of the April Warrants of $380,600 for the year ended December 31, 2020 is included in other income (expense) in the consolidated 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, 2021 and 2020, the recorded values of cash and cash equivalents, restricted deposit, accounts payable, accrued expenses and convertible promissory notes approximated 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 statement. Offering costs incurred prior to an offering are initially capitalized and then subsequently reclassified to additional paid-in capital upon completion of the offering. If the equity offering is not completed, any costs deferred will be expensed immediately upon termination of the offering.

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 $470,000 and $434,000 for the years ended December 31, 2021 and 2020, 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, 2021 and 2020, 43.9 million and 56.4 million shares, respectively, underlying potentially dilutive 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,	
	2021	2020
Options outstanding under the Private Innovate Plan	5,300,518	6,028,781
Options outstanding under the Omnibus Plan	14,608,442	10,598,426
Options outstanding under the Option Grant Agreements granted to RDD Employees	985,807	1,014,173
Warrants outstanding at a weighted-average exercise price of $55.31	—	154,403
Warrants outstanding at an exercise price of $2.54	2,233	2,233
Warrants outstanding at an exercise price of $3.18	113,980	113,980
Warrants outstanding at an exercise price of $0.5894	22,927,849	38,457,000
Total	43,938,829	56,368,996

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 consolidated 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, 2021 and 2020, 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 the Company's primary operations are in North America.

Recently Issued Accounting Standards

Accounting Pronouncements Adopted

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 exceptions 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. The Company adopted this guidance effective January 1, 2021 and the adoption of ASU 2019-12 did not have a material impact on the Company's consolidated financial statements.

Accounting Pronouncements Being Evaluated

In August 2020, the FASB issued ASU 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts in an entity's own equity. Among other changes, ASU 2020-06 removes from U.S. GAAP the liability and equity separation model for convertible instruments with a cash conversion feature, and as a result, after adoption, entities will no longer separately present in equity an embedded conversion feature for such debt. ASU 2020-06 also enhances transparency and improves disclosures for convertible instruments and earnings per share guidance. ASU 2020-06 is effective for fiscal years beginning after December 15, 2021, with early adoption permitted for fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact this standard will have on the Company's consolidated 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. During the year ended December 31, 2021, the Company raised capital from the April 2021 Offering of approximately $34.5 million and received proceeds from the exercise of warrants of approximately $9.2 million. The Company expects to incur substantial losses in the future as it progresses its current product pipeline, seeks regulatory approval for product candidates and prepares for commercialization.

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 future operating activities. 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. The accompanying consolidated financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

The Company may seek to raise additional funding through dilutive and non-dilutive financings. 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 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.

NOTE 3: MERGER AND ACQUISITION

Lobesity Acquisition

On July 19, 2021, the Company closed an Asset Purchase Agreement with Lobesity LLC ("Lobesity") pursuant to which the Company acquired global development rights to a proprietary and highly specific humanized monoclonal antibody that targets glucose-dependent insulinotropic polypeptide, as well as related intellectual property (the "Lobesity Acquisition"). The consideration for the Lobesity Acquisition at closing consisted of $2.3 million in cash and 2,417,211 shares of unregistered common stock plus the right to contingent payments including certain potential worldwide regulatory and clinical milestone payments totaling $45.5 million for a single indication (with the total amount payable, if multiple indications are developed, not to exceed $58.0 million), global sales-related milestone payments totaling up to $50.0 million, and, subject to certain adjustments, a mid-single digit royalty on worldwide net sales.

To satisfy the Company's post-closing rights to indemnification under the Asset Purchase Agreement, 604,303 of the shares issued to Lobesity are subject to holdback restrictions for 18 months following closing of the transaction. The Company's right to indemnification will be satisfied through the recovery of these shares or paid in cash by Lobesity.

RDD Merger

On April 30, 2020, the Company completed its merger with RDD. Upon closing of the RDD Merger, the Company issued the RDD shareholders upfront consideration consisting of 37,860,510 shares of the Company's common stock. In addition, the Company assumed 1,014,173 options that had been previously issued to RDD employees. See Note 9—Share-based Compensation for additional details regarding the options assumed.

Naia Acquisition

On May 6, 2020, the Company consummated its merger with Naia Rare Diseases, Inc. in accordance with the terms of an Agreement and Plan of Merger (the "Naia Acquisition"). The consideration for the Naia Acquisition at closing consisted of $2.1 million in cash and 4,835,438 shares of common stock, plus the pre-payment of certain operating costs on behalf of Naia totaling $0.1 million. Consideration for the Naia Acquisition also included future development and sales milestone payments worth up to $80.4 million and royalties on net sales of certain products to which Naia has exclusive rights by license.

Accounting Treatment

The Lobesity Acquisition, RDD Merger and the Naia Acquisition were each accounted for as asset acquisitions under ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. The net tangible and intangible assets acquired, and liabilities assumed in connection with the transactions were recorded at their estimated fair values on the respective dates of acquisition. The excess of purchase price over fair value of identified assets acquired and liabilities assumed was expensed as in-process research and development.

During the year ended December 31, 2021, the Company acquired the Lobesity asset for $2.3 million cash and shares of the Company's common stock valued at approximately $2.6 million. In addition, the Company paid approximately $0.2 million in transaction costs associated with the Lobesity Acquisition. There was no contingent consideration recorded at the time of the Lobesity Acquisition because the related development, regulatory and sales milestones were not deemed probable.

During the year ended December 31, 2020, the Company acquired the RDD net assets for shares of the Company's common stock valued at $26.6 million and assumed liabilities of $1.3 million. The net assets received were less than $0.1 million. During the year ended December 31, 2020, the Company acquired the Naia technology for $2.1 million in cash, common stock valued at $2.2 million, excluding contingent consideration, and the pre-payment of certain operating costs on behalf of Naia totaling $0.1 million. No contingent consideration associated with the Naia Acquisition was recorded at the time of acquisition because the related development and sales milestones were not deemed probable.

NOTE 4: PROPERTY AND EQUIPMENT

Property and equipment consisted of the following as of December 31, 2021 and 2020:

	December 31,	
	2021	**2020**
Furniture and fixtures	$ 11,552	$ 11,552
Computer equipment	43,578	31,102
Leasehold improvements	29,994	29,994
Property and equipment, gross	$ 85,124	$ 72,648
Less: Accumulated depreciation	(69,030)	(61,457)
Property and equipment, net	$ 16,094	$ 11,191

Depreciation expense for property and equipment was approximately $7,600 and $18,000 for the years ended December 31, 2021 and 2020, respectively.

NOTE 5: RELATED PARTY TRANSACTIONS

Master Services Agreement

Michael Rice, a member of our Board since March 2021, is a Founding Partner of LifeSci Advisors, LLC and LifeSci Communications, LLC. Prior to his becoming a director, on April 1, 2020 the Company entered into a master services agreement with both LifeSci Advisors, LLC and LifeSci Communications, LLC, to provide investor relations and public relations services, respectively. The Company incurred expenses of approximately $0.3 million with LifeSci Advisors, LLC and approximately $0.3 million with LifeSci Communications, LLC during the year ended December 31, 2021. LifeSci Advisors, LLC and LifeSci Communications, LLC were not related parties during the year ended December 31, 2020.

Equity Financing

On May 4, 2020, the Company closed the RDD Merger Financing and the Company sold an aggregate of (i) 382,779 shares of Series A Preferred Stock, par value $0.0001 per share, which converted into 38,277,900 shares of common stock on June 30, 2020, upon receipt of approval by the Company's stockholders, and (ii) Preferred Warrants to purchase up to 382,779 shares of Series A Preferred Stock, which following the Automatic Conversion became exercisable for 38,277,900 shares of common stock. The Company's Chief Executive Officer, Chief Financial Officer and members of the Board

(collectively referred to as the "9 Meters Purchasers"), purchased an aggregate of 75,073 shares of preferred stock (that subsequently converted into 7,507,300 shares of common stock) in the offering at the public offering price and on the same terms as the other purchasers in the offering. The underwriters received the same underwriting discount on the shares purchased by the 9 Meters Purchasers as the other shares sold in the offering. The aggregate purchase price of the common stock units issued to the 9 Meters Purchasers was approximately $4.4 million.

Pursuant to the December Underwriting Agreement in connection with the December 2020 Offering, the Company issued an aggregate of 53,076,924 shares of common stock at a price of $0.65 per share. Of the shares issued in the December 2020 Offering, the Company's Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors purchased an aggregate of 446,153 shares of common stock in the offering at the public offering price and on the same terms as the other purchasers in the offering. The underwriters received the same underwriting discount on the shares purchased by the Company's Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors as the other shares sold in the offering. The aggregate purchase price of the common stock shares issued to the Company's Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors was approximately $290,000.

Pursuant to the March Underwriting Agreement in connection with the April 2021 Offering, the Company issued an aggregate of 34,500,000 shares of common stock at a price of $1.00 per share. Of the shares issued in the April 2021 Offering, the Company's Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors purchased an aggregate of 450,000 shares at the public offering price and on the same terms as the other purchasers in the April 2021 Offering. The underwriters received the same underwriting discount on the shares purchased by the Company's Chief Executive Officer, Chief Financial Officer and Chairman of the Board of Directors as the other shares sold in the offering. The aggregate purchase price of the common stock shares issued to the Company's Chief Executive Officer, Chief Financial Officer and Chairman of the Board was $450,000.

NOTE 6: DEBT

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 had the right to 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 purchase price of the Unsecured Convertible Note was $5.0 million, and the Unsecured Convertible Note carried an original issuance discount ("OID") of $0.5 million, which was included in the principal amount of the Unsecured Convertible Note.

As a result of the redemption features of the Unsecured Convertible Note, the Company amortized the debt issuance costs and accreted 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 were 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 the debt discount and accretion of the OID for the Unsecured Convertible Note recorded as interest expense was approximately $0.8 million for the year ended December 31, 2020. The Unsecured Convertible Note was paid in full as of December 31, 2020 and there was no interest expense associated with the Unsecured Convertible Note during the year ended December 31, 2021.

The Unsecured Convertible Note bore interest at the rate of 10% per annum, compounding on a daily basis. During the year ended December 31, 2020, the Company made principal payments of $4.1 million on the Unsecured Convertible Note, consisting of $1.5 million in cash payments and $2.6 million in stock conversions. During the year ended December 31, 2020, the remaining principal of $2.6 million and accrued interest of $0.1 million were converted into 6,583,143 shares of the Company's common stock at a weighted-average conversion price of $0.42, which reflected a discount of approximately 38% (the "Conversion Discount"). The Conversion Discount represented a beneficial conversion feature of approximately $1.4 million which was recorded as a charge to interest expense and a credit to additional paid-in capital in the accompanying consolidated financial statements.

Standstill Agreement

On April 3, 2020, the Company entered into a standstill agreement with the Convertible Noteholder (the "Standstill Agreement"). Pursuant to the Standstill Agreement, the Convertible Noteholder would not seek to redeem any portion of the Unsecured Convertible Note between April 1, 2020 and May 31, 2020. The outstanding balance of the Unsecured Convertible Note was increased by $150,000 on April 3, 2020 as consideration for the Standstill Agreement and was recorded as interest expense during the year ended December 31, 2020. All other terms of the Unsecured Convertible Note remained in full force and effect.

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 could 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 purchase price of the Additional Note was $2,500,000 and carried an original issuance discount of $250,000, which was included in the principal amount of the Additional Note.

The various conversion and redemption features contained in the Additional Note were embedded derivative instruments, which were recorded as a debt discount and derivative liability at the issuance date at their estimated fair value of $0.4 million. Amortization of the debt discount and accretion of the OID for the Additional Note recorded as interest expense was approximately $44,000 and $0.6 million for the years ended December 31, 2021 and 2020, respectively.

The Additional Note bore interest at the rate of 10% per annum, compounding on a daily basis. During the year ended December 31, 2020, the Company made principal payments on the Additional Note of approximately $2.7 million, consisting of $1.0 million in cash payments and $1.7 million in stock conversions. The principal of $1.7 million and accrued interest of $0.2 million were converted into 4,266,964 shares of the Company's common stock at a weighted-average conversion price of $0.45, which reflected a discount of approximately 36%. The conversion discount represented a beneficial conversion feature of approximately $0.8 million which was recorded as a charge to interest expense and a credit to additional paid-in capital in the accompanying consolidated financial statements.

The convertible notes payable as of December 31, 2020 consisted of the following:

	December 31, 2020
Convertible notes payable, net	$ 8,400,000
Less: principal payments of debt	(8,341,801)
Less: unamortized debt discount and OID	(43,983)
Total	$ 14,216

During January 2021, the Company paid the remaining balance of principal and interest on the Additional Note of approximately $59,000. The payment was made in cash and the Additional Note is paid in full.

NOTE 7: LICENSE AGREEMENTS

Alba License

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.

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.

Seachaid Agreement

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.

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.

Repligen Agreement

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. 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.

Amunix Licenses

In connection with the Naia Acquisition, the Company entered into two amended and restated license agreements with Amunix Pharmaceuticals, Inc. ("Amunix"), pursuant to which the Company received an exclusive, worldwide, royalty-bearing license, with rights of sublicense, to lead molecules GLP-1 and GLP-2 along with a related XTEN sequence and other intellectual property referenced therein (the "Amunix Licenses"). Also in connection with the Naia Acquisition, the Company entered into an amended and restated license agreement with Cedars-Sinai Medical Center ("Cedars"), pursuant to which the Company licensed the rights to GLP-1 Agonist for the treatment of SBS (the "Cedars License").

As consideration under the Amunix License for GLP-1, the Company agreed to pay Amunix certain royalty payments and (i) $70.4 million in milestone payments upon achievement of future development and sales milestones in the U.S. and major EU countries, (ii) $20.5 million in milestone payments upon achievement of future development and sales milestones in China and certain related territories, and (iii) $20.5 million in milestone payments upon achievement of future development and sales milestones in South Korea and certain other East Asian countries. As consideration under the Amunix License for GLP-2, the Company agreed to pay Amunix certain royalty payments and $60.1 million in milestone payments upon achievement of future development and sales milestones in the U.S. and major EU countries.

As consideration under the Cedars License, the Company agreed to pay Cedars certain royalty payments and approximately $9.4 million in milestone payments upon achievement of future development and sales milestones.

MHS License

One of the assets acquired in the Lobesity Acquisition was an amended and restated technology license agreement with MHS Care-Innovation LLC ("MHS"), pursuant to which the Company received an exclusive, worldwide license, with rights to sublicense, to certain patent and other intellectual property rights concerning a proprietary and highly specific humanized monoclonal antibody that targets glucose-dependent insulinotropic polypeptide (the "MHS License"). The MHS License does not require the payment of any future milestone payments or royalties to MHS, since it was originally entered into with Lobesity in exchange for the issuance of certain equity securities and a grant of certain related rights to Lobesity, all of which occurred prior to the closing of the Lobesity Acquisition. As consideration for the assets purchased in the Lobesity Acquisition (including but not limited to the MHS License), the Company is obligated to pay Lobesity (i) potential worldwide regulatory and clinical milestone payments totaling $45.5 million for a single indication (with the total amount payable, if multiple indication are developed, not to exceed $58.0 million), (ii) up to $50.0 million in global sales-related milestone payments, and (iii) subject to certain adjustments, a mid-single digit royalty on worldwide net sales.

EBRIS Collaboration

On August 6, 2021, the Company announced a collaboration with the European Biomedical Research Institute of Salerno, Italy (EBRIS) to study larazotide for the treatment of multisystem inflammatory syndrome in children ("MIS-C"). In connection with this collaboration, the Company paid a milestone fee of $0.5 million upon IND approval for MIS-C. Following receipt of a Study May Proceed letter from the FDA under the Investigator IND, EBRIS initiated a Phase 2a study in MIS-C during the fourth quarter of 2021. The Phase 2a study is a randomized, double-blind, placebo-controlled study, which if successful, could lead to further discussions between the Company, EBRIS and regulators as to the best path forward to develop larazotide in MIS-C.

Milestone Fees

The Company incurred total milestone fees of approximately $0.6 million and $2.2 million during the years ended December 31, 2021 and 2020, respectively.

NOTE 8: STOCKHOLDERS' EQUITY (DEFICIT)

The Company's amended and restated certificate of incorporation, as amended in June 2021, authorizes 560 million shares of capital stock, par value $0.0001 per share, of which 550 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. On April 29, 2020, the Board designated 600,000 shares of preferred stock as Series A Preferred Stock, par value of $0.0001 per share.

On May 4, 2020, the Company closed the RDD Merger Financing, further described in Note 1—Summary of Significant Accounting Policies, pursuant to which the Company sold an aggregate of 382,779 shares of Series A Preferred Stock, par value $0.0001, which were convertible into 38,277,900 shares of common stock and Preferred Warrants to purchase up to 382,779 shares of Series A Preferred Stock, which became exercisable for 38,277,900 shares of common stock. The Series A Preferred Stock was classified as equity in accordance with ASC 480—*Distinguishing Liabilities from Equity*. Shares of the Series A Preferred Stock and the Preferred Warrants were valued using the relative fair value method. The Preferred Warrants were valued using a Black Scholes option pricing model. The Company determined the transaction created a beneficial conversion feature of approximately $3.1 million. The table below summarizes the inputs for the Black Scholes option pricing model on the date of issuance:

	May 4, 2020	
Conversion price	$ 0.5894	
Expected stock price volatility	73.7	%
Risk-free interest rate	0.4	%
Expected term		5 years
Price of the underlying common stock	$ 0.50	

As of May 4, 2020, the stated value of the issued and outstanding Series A Preferred Stock and the Preferred Warrants was approximately $12.5 million and $7.0 million, respectively. On June 30, 2020, the Company's outstanding Series A Preferred Stock automatically converted into 38,277,900 shares of common stock upon receipt of stockholder approval. Each share of outstanding Series A Preferred Stock converted into 100 shares of Common Stock and each share of Series A Preferred Stock underlying the Preferred Warrants became exercisable for 100 shares of Common Stock. Upon conversion of the Series A Preferred Stock, the Company reclassified the carrying value of the Series A Preferred Stock to common stock and additional paid-in capital.

There were no shares of preferred stock issued and outstanding as of December 31, 2021 and 2020.

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 258,235,418 and 204,629,064 shares of common stock outstanding as of December 31, 2021 and 2020, respectively. The Company had reserved shares of common stock for future issuance as follows:

	December 31,	
	2021	**2020**
Outstanding stock options	20,894,767	17,641,380
Warrants to purchase common stock	23,044,062	38,727,616
Restricted stock units subject to vest	—	203,667
Shares issuable upon conversion of convertible debt	—	18,057
For possible future issuance under the Omnibus Plan	5,478,787	9,576,451
Total common shares reserved for future issuance	49,417,616	66,167,171

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 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. During the year ended December 31, 2020, the Company issued 1,847,309 shares of common stock in exchange for cancellation and termination of the remaining outstanding Exchange Warrants. As of December 31, 2020, all of the April Warrants and Placement Agent Warrants had been exchanged for Common Stock and there were no April Warrants or Placement Agent Warrants outstanding.

On April 29, 2020, pursuant to the Offer to Amend and Exercise further described in Note 1—Summary of Significant Accounting Policies, warrants to purchase an aggregate of 12,230,418 shares of common stock were tendered, amended and exercised for aggregate gross proceeds of approximately $1.2 million.

The Company entered into a sales agreement dated July 22, 2020, as amended on October 2, 2020, with Truist relating to an ATM pursuant to which the Company may sell, from time to time, common stock with an aggregate offering price of up to $40 million through Truist, as sales agent, for general corporate purposes (the "2020 ATM"). During the year ended December 31, 2020, the Company sold 3,496,045 shares under the 2020 ATM for total net proceeds of approximately $2.6 million. Pursuant to the sales agreement, the Company will pay Truist a commission rate of 3.0% of the gross proceeds from the sale of any shares of common stock under the 2020 ATM. There were no shares sold under the 2020 ATM during the year ended December 31, 2021.

NOTE 9: SHARE-BASED COMPENSATION

The Company has two stock option plans in existence: the 2012 Omnibus Incentive Plan, as amended (the "Omnibus Plan") and the Innovate 2015 Stock Incentive Plan (the "Private Innovate Plan"). In addition, the Company assumed 1,014,173 options in accordance with the terms of the RDD Merger Agreement. The Company's stock options typically vest over a period of three or four years and typically have a maximum term of ten years.

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, 2020, the number of shares of

common stock available under the Omnibus Plan automatically increased by 1,973,883 shares, pursuant to the Evergreen Provision. Additionally, on June 30, 2020, stockholders approved an amendment to the Omnibus Plan to increase the aggregate number of shares of common stock available under the Omnibus Plan by 15,000,000 shares. The Board elected to forgo the increase from the Evergreen Provision that would have increased the option pool by 5% of the shares of common stock outstanding on January 1, 2021. See Note 12—Subsequent Events for further details regarding the increase from the Evergreen Provision on January 1, 2022.

Private Innovate Plan

As of December 31, 2021, there were 5,300,518 stock options outstanding under the Private Innovate Plan. Since 2018, the Company has not issued, and does not intend to issue, any additional awards from the Private Innovate Plan.

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

	Number of Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2020	6,028,781	$ 1.53	$ 1,080,474	3.2
Options granted	—	—		—
Options forfeited	(5,652)	2.08		—
Options exercised	(722,611)	0.36		—
Outstanding at December 31, 2021	5,300,518	1.69	837,459	2.7
Exercisable at December 31, 2021	5,300,518	1.69	837,459	2.7
Vested and expected to vest at December 31, 2021	5,300,518	$ 1.69	$ 837,459	2.7

There were no options granted under the Private Innovate Plan during the years ended December 31, 2021 and 2020. The total intrinsic value of options exercised was approximately $635,000 during the year ended December 31, 2021. There were no options exercised during the year ended December 31, 2020.

The total fair value of stock option awards vested during the years ended December 31, 2021 and 2020 under the Private Innovate Plan was approximately $49,000 and $508,000, respectively. As of December 31, 2021, there was no unrecognized compensation cost related to unvested stock-based compensation arrangements under the Private Innovate Plan.

The Private Innovate Plan provides for accelerated vesting under certain change-of-control transactions, if approved by the Board. On April 23, 2021, the Board approved the extension of the exercise periods of certain option holders' vested options for an additional twelve months. Pursuant to the Board's approval, options to purchase 1,708,270 shares of the Company's common stock were extended and the Company recognized an additional $0.3 million in non-cash stock compensation expense related to the modification during the year ended December 31, 2021. All other terms of the options remained unchanged.

Omnibus Plan

As of December 31, 2021, there were options to purchase 14,608,442 shares of the Company's common stock outstanding under the Omnibus Plan and 5,478,787 shares available for future grants under the Omnibus Plan.

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

	Year Ended December 31,	
	2021	2020
Expected dividend yield	0%	0%
Expected stock-price volatility	68% - 85%	68% - 85%
Risk-free interest rate	0.1% - 1.1%	0.1% - 0.7%
Expected term of options (in years)	2.3 - 6.1	5.0 - 10.0

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

	Number of Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2020	10,598,426	$ 1.01	$ 1,490,488	9.2
Options granted	4,355,747	1.63		
Options forfeited	(258,083)	1.24		
Options exercised	(87,648)	0.78		
Outstanding at December 31, 2021	14,608,442	1.19	2,296,720	8.5
Exercisable at December 31, 2021	6,123,367	1.19	1,194,586	8.0
Vested and expected to vest at December 31, 2021	14,085,335	$ 1.18	$ 2,231,080	8.5

The weighted-average grant date fair value of options granted under the Omnibus Plan was $0.90 and $0.38 during the years ended December 31, 2021 and 2020, respectively. The total intrinsic value of options exercised was approximately $39,000 during the year ended December 31, 2021. There were no options exercised during the year ended December 31, 2020.

The total fair value of stock option awards vested under the Omnibus Plan was approximately $823,000 and $1,946,000 during the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, there was approximately $5.2 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 2.9 years.

The Omnibus Plan provides for accelerated vesting under certain change-of-control transactions, if approved by the Board. Upon expiration of the term of one of the Company’s former directors, the Board approved the acceleration and extension of unvested options held by the former director. The Company recognized an additional $0.1 million in non-cash stock compensation expense related to the modification during the year ended December 31, 2021. Upon consummation of the RDD Merger on April 30, 2020, the Board approved the acceleration of certain options for employees, directors and key consultants. The Company recognized an additional $2.7 million in non-cash stock compensation expense related to the modification during the year ended December 31, 2020.

There were no RSUs granted during the year ended December 31, 2021. During the year ended December 31, 2020, the Board approved grants of 415,948 RSUs, which vested immediately upon the date of grant and 203,667 RSUs which vested on the one-year anniversary from the date of grant. The weighted-average fair value of RSUs granted during the year ended December 31, 2020 $0.74. The Company recognized share-based compensation expense for the RSUs of approximately $198,000 and $275,000 during the years ended December 31, 2021 and 2020, respectively.

RDD Option Grants

Pursuant to the RDD Merger Agreement, the Company assumed option grant agreements for 1,014,173 shares awarded to RDD employees upon consummation of the RDD Merger (the "RDD Options") on April 30, 2020. There were 985,807 RDD Options outstanding as of December 31, 2021 at a weighted-average exercise price of $0.63 per share. All of the RDD Options are fully vested as of December 31, 2020 and there were no RDD Options granted during the year ended December 31, 2021. The total fair value of RDD Options vested during the year ended December 31, 2020 was approximately $471,000. The total intrinsic value of RDD Options exercised was approximately $27,000 during the year ended December 31, 2021. There were no RDD Options exercised during the year ended December 31 2020. The range of assumptions used in estimating the fair value of the RDD Options using the Black-Scholes option pricing model for the period presented were as follows:

	Year Ended December 31, 2020
Expected dividend yield	— %
Expected stock-price volatility	72% - 74%
Risk-free interest rate	0.4% - 0.6%
Expected term of options (in years)	5.0 - 10.0

The following table summarizes stock option activity for the RDD Options:

	Number of Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2020	1,014,173	$ 0.63	$ 228,860	4.3
Options granted	—	—		
Options forfeited	—	—		
Options exercised	(28,366)	0.74		
Outstanding at December 31, 2021	985,807	0.63	343,486	3.3
Exercisable at December 31, 2021	985,807	0.63	343,486	3.3
Vested and expected to vest at December 31, 2021	985,807	$ 0.63	$ 343,486	3.3

Share-based Compensation Expense

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

	Year Ended December 31,	
	2021	2020
Research and development	$ 773,000	$ 1,820,000
General and administrative	1,640,000	2,903,000
Total share-based compensation	$ 2,413,000	$ 4,723,000

NOTE 10: INCOME TAXES

No provision for federal and state income tax expense has been recorded for the years ended December 31, 2021 and 2020 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,	
	2021	2020
Domestic tax loss and contribution carryforwards	$ 18,656,500	$ 13,798,700
Foreign tax loss carryforwards	5,134,700	4,587,100
Tax credits	2,534,600	1,358,200
Share-based compensation	3,647,100	3,864,900
Intangible assets	3,096,800	3,139,400
Accrued expenses	371,200	88,500
Legal fees	—	40,200
Research and development expenses	20,500	204,800
Other	5,900	6,900
Valuation allowance	(33,467,300)	(27,088,700)
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, 2021 and 2020, the valuation allowance increased by $6,265,600 and $7,240,100, respectively.

The reasons for the difference between actual income tax expense (benefit) for the years ended December 31, 2021 and 2020, and the amount computed by applying the statutory federal income tax rate to losses before income tax (benefit) are as follows:

	2021		2020	
	Amount	% of Pretax Earnings	Amount	% of Pretax Earnings
Income tax benefit at statutory rate	$ (7,726,800)	21.0 %	$ (12,914,300)	21.0 %
State income taxes, net of federal tax benefit	(27,900)	0.1 %	(661,300)	1.1 %
Non-deductible expenses	4,500	0.0 %	1,337,100	(2.2)%
In-process research and development expenses	—	— %	6,425,000	(10.4)%
Credits	(1,176,500)	3.2 %	(634,400)	1.0 %
Foreign rate differential	2,400	— %	(562,600)	0.9 %
Change in state tax rate	1,764,100	(4.8)%	(1,400)	— %
Other	894,600	(2.5)%	107,400	(0.1)%
Change in valuation allowance	6,265,600	(17.0)%	6,904,500	(11.3)%
Income tax benefit	$ —	— %	$ —	— %

As of December 31, 2021, the Company had net operating loss carryforwards for federal, state and foreign income tax purposes of $88,722,200, $88,568,100 and $30,689,600 respectively. Federal loss carryforwards of $3,551,900 begin to expire in 2034 and $85,170,300 of the federal losses carryforward indefinitely. The state loss carryforwards begin to expire in 2029. Foreign net operating losses carry forward indefinitely, and may be subject to limitation. As of December 31, 2021, the Company had contribution carryforwards of $11,000, which begin to expire in 2023. In addition, as of December 31, 2021, the Company has federal research and development credits of $2,534,600 which begin to expire in 2038.

The Company acquired a subsidiary in Israel during the year ended December 31, 2020. However, the subsidiary has a history of book losses and as such, has no undistributed earnings.

The Tax Cuts and Jobs Act subjects a US shareholder to tax on global intangible low-taxed income ("GILTI") earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740, No. 5, *Accounting for Global Intangible Low-Taxed Income*, states that an entity can make an accounting policy election to either recognized deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense only. The Company has elected to account for GILTI in the year the tax is incurred. The Company does not have a GILTI inclusion in 2021 or 2020; therefore, no GILTI tax has been recorded for the years ended December 31, 2021 and 2020.

On November 18, 2021, Governor Roy Cooper signed into law the 2021 Appropriations Act which phases out the corporate income tax for North Carolina. The Bill phases out the current 2.5% North Carolina corporate income tax rate over five years starting in 2025, reaching zero by 2030. For tax years beginning on or after January 1, 2025 the rate is 2.25%. The rate decreases to 2% in 2026 and 2027; and to 1% in 2028 and 2029. After 2029, the rate decreases to 0%. As a result of the revised tax rate, the Company adjusted its North Carolina net operating loss deferred tax asset as of December 31, 2021 by applying the revised tax rate, which resulted in a decrease to the deferred tax assets and a corresponding decrease to the valuation allowance of approximately $1.8 million.

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, 2021 and 2020, 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, 2021 and 2020, the Company did not record any interest and penalties related to uncertain tax positions.

NOTE 11: COMMITMENTS AND CONTINGENCIES

Employment Agreements

The Company has entered into executive employment agreements with the 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 such executive is terminated under certain conditions that would provide the executive with up to 18 months of their base salary and up to 12 months of continuation of health insurance benefits.

Periodically, the Company enters into separation and general release agreements with former executives of the Company that include separation benefits consistent with the former executives' employment agreements. The Company recognized severance expense totaling $0.4 million and $0.8 million during the years ended December 31, 2021 and 2020, which is paid in equal installments over 12 months from the date of separation. The accrued severance obligation was approximately $0.4 million as of December 31, 2021.

Office Lease

In July 2020, the Company entered into a 4-year lease for office space that expires on September 30, 2024. Base annual rent is $72,000, or $6,000 per month. Monthly payments of $6,000 are due and payable over the 4-year term. The lease contains a 3-year renewal option. The Company recorded a right of use asset of $233,206 and an operating lease liability of $233,206 at the inception of the lease in July 2020.

The Company estimated the present value of the lease payments over the remaining term of the leases using a discount rate of 12%, which represented the Company's estimated incremental borrowing rate. The renewal options were excluded from the lease payments as the Company concluded the exercise of the option was not considered reasonably certain.

Operating lease cost under ASC 842 was approximately $71,520 and 64,800 for the years ended December 31, 2021 and 2020, respectively. Operating lease cost is included in general and administrative expenses on the accompanying consolidated statement 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, 2021.

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

Year ending December 31,	**Operating Leases**
2022	$ 72,000
2023	72,000
2024	54,000
Total lease payment	198,000
Less: imputed interest	(30,062)
Total	$ 167,938

Legal

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

Evergreen Provision

On January 1, 2022, the number of shares of common stock available under the Omnibus Plan automatically increased by 12,911,771 shares pursuant to the Evergreen Provision.

Severance Agreement

On January 14, 2022 (the "Separation Date"), the Company entered into a separation and consulting agreement with its former Chief Financial Officer (the "Separation Agreement"). Pursuant to the Separation Agreement, the former executive is serving as an independent consultant for three months following the Separation Date (the "Consulting Period"). In connection with the separation, the former executive will receive: (i) separation pay in an amount equal to 12 months of his regular base salary, minus applicable withholdings, paid in accordance with the Company's normal payroll practices; (ii) payment of his 2021 annual bonus, as determined by the Board; and (iii) payment of his 2022 annual bonus prorated for his period of service prior to the Separation Date and during the Consulting Period. The material terms of the former executive's previously granted equity awards subject to time-based vesting will continue to vest in accordance with the applicable vesting schedule over the course of the Consulting Period. Upon completion of the Consulting Period, the Company will accelerate the vesting of all remaining unvested options and extend the exercise period to ten years from the issuance date. All separation benefits were subject to the former executive entering into and not revoking the Separation Agreement.

FIRST AMENDMENT TO EMPLOYMENT AGREEMENT

THIS FIRST AMENDMENT TO EMPLOYMENT AGREEMENT (this "Amendment") is entered into effective as of July 12, 2021 (the "Amendment Effective Date"), by and between 9 Meters Biopharma, Inc. (f/k/a Innovate Biopharmaceuticals, Inc.), a Delaware corporation (the "Company") and John Temperato (the "Executive").

WITNESSETH:

WHEREAS, Executive and the Company entered into an Employment Agreement dated as of April 30, 2020 (the "Employment Agreement") pursuant to which Executive was hired to serve as the Chief Executive Officer of the Company (as such term is defined in the Employment Agreement);

WHEREAS, Executive and the Company wish to amend certain terms of the Employment Agreement regarding compensation to be paid to Executive in the event of certain terminations of employment following a Change in Control as well as the meaning of the term Good Reason as used in the Employment Agreement; and

WHEREAS, in light of the foregoing, Executive and the Company desire to mutually and voluntarily amend the Employment Agreement pursuant to the terms as set forth herein.

NOW, THEREFORE, in consideration of the foregoing, the mutual promises herein contained, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, agree as follows.

1. AMENDMENT TO SECTION 5(a)(i) OF THE EMPLOYMENT AGREEMENT. Effective as of the Amendment Effective Date, Section 5(a)(i) of the Employment Agreement is modified by deleting the existing Section 5(a)(i) and replacing it with a new Section 5(a)(i) as follows:

"(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 (it being understood that either (y) Executive's ceasing to be Chief Executive Officer of a publicly-traded company immediately following a Change in Control (as such term is defined in the Company's 2012 Omnibus Incentive Plan, as amended) or (z) a change in Executive's reporting structure so that he reports to a person or group of persons other than the Board, will constitute Good Reason under this clause (A)); (B) the Executive's Base Salary is reduced by more than fifteen percent (15%) from the level prior to such reduction, except for an across the board reduction in base salary for all similarly situated executives; (C) the Company materially breaches its obligations under this Agreement; or (D) the Executive's place of employment is relocated by more than fifty (50) miles. In addition to the requirements set forth above, in order to resign for Good Reason, (X) the Executive must inform the Company of the existence of the event within ninety (90) days of the initial existence of the event, (Y) the Company must fail to cure such condition which otherwise would constitute "Good Reason" hereunder within thirty (30) days after such notice, and (Z) the Executive must terminate employment with the Company

for such “Good Reason” no later than thirty (30) days after the conclusion of the Company’s cure period.”

2. AMENDMENT TO SECTION 5(c) OF THE EMPLOYMENT AGREEMENT. Effective as of the Amendment Effective Date, Section 5(c) of the Employment Agreement is modified by deleting the existing Section 5(c) and replacing it with a new Section 5(c) as follows:

“(c) Obligations of the Company Upon Termination.

(i) Upon the termination of this Agreement: (A) by the Executive pursuant to paragraph 5(a)(ii); or (B) by the Company pursuant to paragraph 5(b)(ii), (iii), or (iv) the Company shall have no further obligations hereunder other than the payment of all compensation and other benefits payable to the Executive through the date of such termination which shall be paid on or before the Company’s next regularly scheduled payday unless such amount is not then-calculable, in which case payment shall be made on the first regularly scheduled payday after the amount is calculable.

(ii) Upon termination of this Agreement: (A) by the Executive pursuant to paragraph 5(a)(i); or (B) by the Company pursuant to paragraph 5(b)(i); and provided in either case that the Executive first executes and does not revoke a release agreement in the form acceptable to the Company within the time period then-specified by the Company but in any event no later than sixty (60) days after the date of termination (the “**Release**”):

(A) the Company shall pay the Executive an amount of severance equal to twelve (12) months of Executive’s then-current Base Salary (less all applicable deductions) over the twelve (12) month 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);

(B) the Company shall pay the Executive a prorated amount of Executive’s target bonus for the year in which such termination occurs, if any, in accordance with and subject to Section 4(b); and

(C) the Company shall accelerate the vesting of Executive’s unvested Options and RSUs, if any, that were scheduled to vest in the twelve (12) month period immediately following the date of such termination;

provided, however, that if the termination described in this paragraph 5(c)(ii) occurs at the time of, or within the twelve (12) months immediately following, a Change in Control (as such term is defined in the Company’s 2012 Omnibus Incentive Plan, as amended), then instead of the benefits described in clauses (A), (B) and (C) above, and conditioned upon Executive first executing and not revoking the Release within the time period then-specified by the Company but in any event no later than sixty (60) days after the date of termination:

(D) the Company shall pay the Executive an amount of severance equal to eighteen (18) months of Executive's then-current Base Salary (less all applicable deductions) over the eighteen (18) month 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);

(E) the Company shall pay the Executive an amount equal to Executive's target bonus as described in Section 4(b) above for the year in which such termination occurs in the Company's first regularly-scheduled payroll after the Release becomes effective and irrevocable; and

(F) the Company shall accelerate the vesting of all of Executive's then-unvested equity awards."

3. REMAINDER OF EMPLOYMENT AGREEMENT. Except as expressly set forth in this Amendment, the provisions of the Employment Agreement remain in full force and effect, in their entirety, in accordance with their terms.

4. MISCELLANEOUS. This Amendment will be governed, construed, and interpreted in accordance with the laws of the State of North Carolina, without giving effect to conflicts of laws principles. The parties agree that this Amendment may only be modified in a writing executed by both parties. This Amendment will be binding upon and will inure to the benefit of the parties hereto and their respective heirs, successors and assigns. This Amendment may be executed in separate counterparts, each of which is deemed to be an original and all of which taken together constitute one agreement. Facsimile or PDF reproductions of original signatures will be deemed binding for the purpose of the execution of this Amendment.

[Signature Page Immediately Follows]

IN WITNESS WHEREOF, the parties have executed this First Amendment to Employment Agreement to be effective as of the day and year first above written.

9 METERS BIOPHARMA, INC.

By: /s/ Edward J. Sitar
Name: Edward J. Sitar
Title: Chief Financial Officer

EXECUTIVE:

/s/ John Temperato
John Temperato

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-228830, 333-215406, 333-234598, 333-228828, 333-245664 and 333-245673 on Form S-8 and in Registration Statement No. 333-231584, 333-238850 and 333-249268 on Form S-3 of our report dated March 23, 2022, (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 consolidated financial statements of 9 Meters Biopharma, Inc., as of and for the years ended December 31, 2021 and 2020, included in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ Mayer Hoffman McCann P.C.

San Diego, California
March 23, 2022

Exhibit 31.1

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

I, John Temperato, certify that:

1. I have reviewed this annual report on Form 10-K of 9 Meters Biopharma, 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/ John Temperato

March 23, 2022

John Temperato
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Bethany Sensenig, certify that:

1. I have reviewed this annual report on Form 10-K of 9 Meters Biopharma, 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/ Bethany Sensenig

March 23, 2022

Bethany Sensenig
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, John Temperato, Chief Executive Officer of 9 Meters Biopharma, 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, 2021 (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 23, 2022

/s/ John Temperato
John Temperato
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, Bethany Sensenig, Chief Financial Officer of 9 Meters Biopharma, 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, 2021 (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 23, 2022

/s/ Bethany Sensenig
Bethany Sensenig
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.