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

FORM 10-K

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

For the fiscal year ended December 31, 2020

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: 001-38022

MATINAS BIOPHARMA HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**No. 46-3011414**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

1545 Route 206 South, Suite 302
Bedminster, New Jersey 07921
(Address of principal executive offices) (Zip Code)

908-443-1860
(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, par value $0.0001	MTNB	NYSE American

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 registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒

Emerging growth company ☐

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

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

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant computed by reference to the price at which the common stock was last sold on June 30, 2020 was approximately $141.9 million.

As of March 24, 2021, there were204,276,412 shares of the registrant's common stock, $0.0001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

MATINAS BIOPHARMA HOLDINGS, INC.

Annual Report on Form 10-K

Fiscal Year Ended December 31, 2020

Table of Contents

PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This report on Form 10-K contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- our ability to raise additional capital to fund our operations and to develop our product candidates;
- our anticipated timing for preclinical development, regulatory submissions, commencement and completion of clinical trials and product approvals;
- our history of operating losses in each year since inception and the expectation that we will continue to incur operating losses for the foreseeable future;
- our dependence on product candidates, including LYPDISO ™ (formerly MAT9001), MAT2203 and MAT2501, which are still in an early development stage;
- our reliance on our proprietary lipid nanocrystal (LNC) platform delivery technology, which is licensed to us by Rutgers University;
- our ability to manufacture GMP batches of our product candidates, including LYPDISO, MAT2203 and MAT2501, which are required for preclinical and clinical trials and, subsequently, if regulatory approval is obtained for any of our products, our ability to manufacture commercial quantities;
- our ability to complete required clinical trials for our lead product candidate and other product candidates and obtain approval from the FDA or other regulatory agents in different jurisdictions;
- our dependence on third parties, including third parties to manufacture our intermediates and final product formulations and third-party contract research organizations to conduct our clinical trials;
- our ability to maintain or protect the validity of our patents and other intellectual property;
- our ability to retain and recruit key personnel;

- our ability to internally develop new inventions and intellectual property;
- interpretations of current laws and the passages of future laws;
- our lack of a sales and marketing organization and our ability to commercialize products, if we obtain regulatory approval, whether alone or through potential future collaborators;

- our ability to successfully commercialize, and our expectations regarding future therapeutic and commercial potential with respect to, our product candidates;
- the accuracy of our estimates regarding expenses, ongoing losses, future revenue, capital requirements and our needs for or ability to obtain additional financing; and
- developments and projections relating to our competitors or our industry; and
- our operations, business and financial results have been and could continue to be adversely impacted by the current public health pandemic related to COVID-19.

These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report on Form 10-K and are subject to risks and uncertainties. We discuss many of these risks in greater detail under "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should read this Annual Report on Form 10-K and the documents that we reference and have filed as exhibits to the Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this Annual Report on Form 10-K by these cautionary statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

Item 1. Business

Company Overview

We are a biopharmaceutical company focused on improving the intracellular delivery of critical therapeutics through our paradigm-changing lipid nanocrystal (LNC) delivery platform. We are also focused on creating value through identifying a partner to continue the development of LYPDISO™ (formerly MAT9001), a next generation, highly purified, prescription-only omega-3 free fatty acid formulation specifically designed for the treatment of cardiovascular and metabolic conditions.

Matinas BioPharma is dedicated to maximizing the value associated with our unique LNC platform delivery technology. This proprietary platform technology, licensed from Rutgers University on an exclusive worldwide basis, nano-encapsulates target molecules in a way that facilitates safe, efficient, and targeted intracellular delivery. Comprised of phospholipids, like phosphatidylserine, and calcium, our LNCs can be differentiated from any other delivery technology today both in terms of how LNCs provide flexibility with route of administration as well as how LNCs gain access to cells and how they can also provide flexibility with route of administration. LNCs have been delivered orally, intramuscularly, intravenously and through inhalation. Because of their unique composition, LNCs can be delivered into a cell through any or all of phagocytosis, membrane fusion, or clathrin-mediated endocytosis.

In addition to efficient intracellular delivery to treat a variety of cell-based pathogens, diseases and conditions, our technology allows for the targeted and safe delivery of pharmaceutical agents directly to sites of infection or inflammation. This highly stable, efficient and broadly applicable drug delivery platform has the potential to deliver a broad range of therapeutic agents, including small molecules, vaccines, peptides and proteins, as well as nucleic acid polymers (e.g., antisense, oligonucleotides, siRNA, mRNA) for use in treating a broad range of inflammatory, infectious and other intracellular diseases (e.g., intracellular pathogen-related, genetic disorders, and cancer).

Our lead drug candidate based on the LNC platform delivery technology is MAT2203, an oral formulation of amphotericin B, a well-known and highly effective, antifungal drug (though frequently associated with significant renal toxicity and currently only available in an intravenous formulation) currently used and approved to treat a variety of invasive, and potentially deadly, fungal infections. MAT2203 has been developed to date with the assistance and financial support of the National Institutes of Allergy and Infectious Disease (NIAID) of the National Institutes of Health (NIH). MAT2203 has been designated as a Qualified Infectious Disease Product (QIDP) with Fast Track Status for the treatment of invasive candidiasis, the treatment of aspergillosis, the prevention of invasive fungal infections in patients who are on immunosuppressive therapy, and, most recently, the treatment of cryptococcosis. While we continue to believe that MAT2203 could become an important solution to the significant unmet medical need to prevent invasive fungal infections in immunosuppressed patients, we also believe there are opportunities for a more rapid approval of MAT2203 for the treatment of certain invasive fungal infections in areas of high unmet medical need.

In partnership with the NIH, we have conducted numerous preclinical studies of MAT2203 in cryptococcal meningitis and demonstrated that MAT2203 was able to (a) cross the blood-brain barrier, (b) effectively treat this infection and (c) eliminate the toxicity normally associated with delivery of amphotericin B intravenously. The NIH has funded a grant submission from the University of Minnesota for a clinical study of MAT2203 in patients with cryptococcal meningitis in Uganda, where this disease is highly prevalent among the human immunodeficiency virus (HIV)-positive community. This study, which has been called the *Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial* (EnACT), initiated in 2019 and currently enrolling patients in Cohort 2 of the trial, is exploring the use of MAT2203 for both induction and maintenance therapy, and we believe that, if positive, it could form the foundation for registrational approval in this indication. Moreover, since this study potentially validates the use of MAT2203 in what is arguably one of the most difficult-to-treat fungal infections, we believe MAT2203 is well-positioned to become a best-in-class antifungal drug for the treatment of invasive fungal infections. Furthermore, a demonstration that MAT2203 can effectively cross the blood-brain barrier in humans could potentially position our LNC platform delivery technology for use with molecules designed to treat other inflammatory diseases of the central nervous system through an oral route of administration. Developing MAT2203 utilizing primarily non-dilutive, government-sponsored, financing allows us to focus our internal cash resources on LYPDISO while advancing MAT2203, MAT2501 and our innovative LNC platform delivery technology.

We are also progressing the development of MAT2501, our oral amikacin development program, which is funded in large part by the Cystic Fibrosis Foundation (CFF) which we are developing for the treatment of non-tuberculous mycobacterial (NTM) infection, a highly prevalent lung infection in patients with underlying cystic fibrosis. We received funding of $3.75 million from the CFF in November 2020 which was based upon the positive preclinical proof-of-concept data generated by Colorado State University testing MAT2501 efficacy against both amikacin-sensitive and resistant strains of infecting organisms in a CF mouse model for NTM infections.

We have been engaged in discussions with various large, well-established and well-financed biotech and global pharmaceutical companies on potential applications of the LNC platform delivery technology.

- In July 2018, we announced a research collaboration with the National Institute of Neurological Disorders and Stroke (NINDS) of the NIH, focused on the development of a novel therapy for the treatment of HIV combining targeted antisense oligonucleotides (ASO) and Matinas' LNC platform delivery technology.
- In January 2019, we announced a research evaluation with a top global pharmaceutical company in which our LNC platform delivery technology would be explored in delivering certain nucleic acid polymers.
- In May 2019, we announced a research collaboration with ViiV Healthcare to develop and evaluate formulations of antiviral drug candidates.
- In December 2019, we announced a feasibility collaboration with Genentech relating to the development of oral formulations of a number of Genentech proprietary compounds applying the LNC platform delivery technology.
- In December 2020, we announced a collaboration with the National Institute of Allergy and Infectious Diseases to evaluate oral formulations of Gilead's antiviral remdesivir utilizing our LNC platform delivery technology.

We continue to evaluate additional potential strategic collaborations with other interested biotech and pharmaceutical partners. These early stage, proof-of-concept evaluations could provide an efficient, less expensive pathway to create numerous strategic verticals in areas of innovative medicine while capitalizing on the development expertise and financial resources of well-established pharmaceutical and biotech companies. Data from these evaluations could position us as a licensor of our LNC platform delivery technology to numerous strategic partners better positioned to absorb the risks and costs of drug development while allowing our company to become a royalty aggregator with the potential to generate upfront license, milestone and royalty payments as we maximize the value of the overall LNC platform delivery technology.

We are also focused on securing value for LYPDISO through a collaboration or partnership in the United States or globally. LYPDISO is a soft gelatin capsule containing a complex mixture of multiple long-chain omega-3 fatty acids, primarily eicosapentaenoic acid (EPA) and docosapentaenoic acid (DPA). There are a number of existing FDA-approved prescription omega-3 products, including Lovaza®, Vascepa® and Epanova®, and this class of drugs has extensive evidence of safety and well-documented clinical efficacy in lowering triglycerides (TGs) in patients with hypertriglyceridemia (HTG). We believe that given LYPDISO's enhanced bioavailability (as a free fatty acid rather than an ethyl ester) and its unique composition (high EPA plus DPA, with very little DHA), it is differentiated from other existing products in the omega-3 class.

Triglycerides (TGs) and cholesterol are integral components of lipoproteins, the primary transport vehicle for lipids in the body. High levels of triglyceride-rich lipoproteins are associated with a substantially increased risk of atherosclerotic cardiovascular disease, and, in the case of very high triglycerides, acute pancreatitis. Triglyceride elevations can be due to both genetic and environmental factors and are frequently associated with comorbid conditions such as diabetes, chronic renal failure, and nephrotic syndrome. Unlike the currently approved pharmaceutical omega-3 products, all of which have been repurposed following clinical failures in their originally intended indications, LYPDISO has been specifically designed and developed to treat HTG, dyslipidemia and other cardiovascular and metabolic conditions.

We had previously been focused on the initial development of LYPDISO for an initial indication for the treatment of severe hypertriglyceridemia (SHTG), which are those patients with triglyceride levels ≥ 500mg/dL, since TG-lowering is a well-accepted surrogate outcome marker of clinical efficacy in these patients. Additionally, the prescription omega-3 product Vascepa has been approved for cardiovascular risk reduction in patients at high cardiovascular risk with TGs ≥ 150 md/dL. The development plan for LYPDISO is via a 505(b)(2) regulatory pathway, which tends to be shorter and less expensive than under Section 505(b)(1) (for new chemical entities that have never been approved in the United States). The 505(b)(2) pathway allows us to rely, at least in part, on U.S. Food and Drug Administration (FDA) findings of safety and/or effectiveness for a previously approved drug. Based on prior written feedback received from the FDA in 2014, and additional verbal and written feedback from FDA in August of 2020, we believe that a 505(b)(2) pathway is possible and appropriate for LYPDISO.

In parallel with the preclinical and clinical studies necessary for FDA approval of LYPDISO, we also recently completed the ENHANCE-IT study, a head-to-head crossover study of LYPDISO vs. Vascepa, which was intended to differentiate LYPDISO from the current leading prescription omega-3 therapy. While the primary endpoint of percent change in TGs from baseline to end-of-treatment did not meet statistical significance in the prespecified pharmacodynamic (PD) population, analysis of the per protocol (PP) population demonstrated statistically significant improvement and superiority of LYPDISO over Vascepa in TGs, total cholesterol and very-low-density lipoprotein (VLDL) cholesterol. A key secondary endpoint in ENHANCE-IT was the measurement of eicosapentaenoic acid, or EPA levels, in the blood, as that has become a key surrogate marker in determining cardiovascular risk reduction. In ENHANCE-IT, plasma EPA concentrations were significantly higher with LYPDISO vs. Vascepa (46% relative percent increase change from baseline EPA level vs. Vascepa) and we believe indicate the potential for superior cardioprotection with LYPDISO vs. Vascepa. Overall, the data from ENHANCE-IT support the pursuit of cardiovascular outcomes indication for LYPDISO. Given the significant time and expense of conducting a cardiovascular outcomes trial, we have determined that a partner will be required to further develop LYPDISO. We have initiated a process to identify and secure a partner over the next few quarters.

Strategy

We are focused on improving the intracellular delivery of critical therapeutics through our paradigm-changing lipid nanocrystal (LNC) drug delivery platform and its application to overcome current challenges in safely and effectively delivering small molecules, nucleic acids, gene therapies, proteins/peptides, and vaccines. We are also focused on creating value through finding a partner to continue the development of LYPDISO, our proprietary, next-generation prescription omega-3 drug, which we believe is differentiated from all other prescription omega-3 products and positioned to potentially demonstrate superior cardioprotective effects.

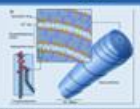
Key elements of our strategy include:

- Advancing our clinical stage assets based on our LNC platform delivery technology and continuing to expand utilization of this promising technology into areas of innovative medicine.
- Delivering efficacy data for MAT2203 in the EnACT study for the treatment of cryptococcal meningitis, which would highlight the safety and efficacy of this promising drug candidate, while demonstrating the ability of our LNC platform technology to deliver potent medicines across the blood-brain barrier with oral administration.
- Progressing the development of MAT2501 through extensive preclinical toxicology and efficacy studies in NTM infections and completing a single ascending dose pharmacokinetic study in healthy volunteers later in 2021, all with the financial support of the Cystic Fibrosis Foundation.

Our Lipid Nanocrystal (LNC) Platform Delivery Technology

Efficient and safe delivery of medicines remains one of the biggest challenges in the pharmaceutical and biotech industry today. The advancement of science and the emerging importance of cell-mediated immunity and current challenges associated with effective intracellular drug delivery has created a significant area of need. Current technology options, including liposomes, lipid nanoparticles (LNPs) and viral vectors, have been widely adopted but each have significant limitations including inefficient delivery, undesirable and dangerous toxicity and immunogenicity, and unstable formulations forcing challenging storage conditions (Figure 1). The method in which these technologies gain access to a cell varies and often is responsible for significant adverse effects for patients. Despite these known challenges, adoption has been widespread due to the lack of viable alternatives. Today, LNPs and viral vectors are being used to deliver both small molecules and gene therapy.

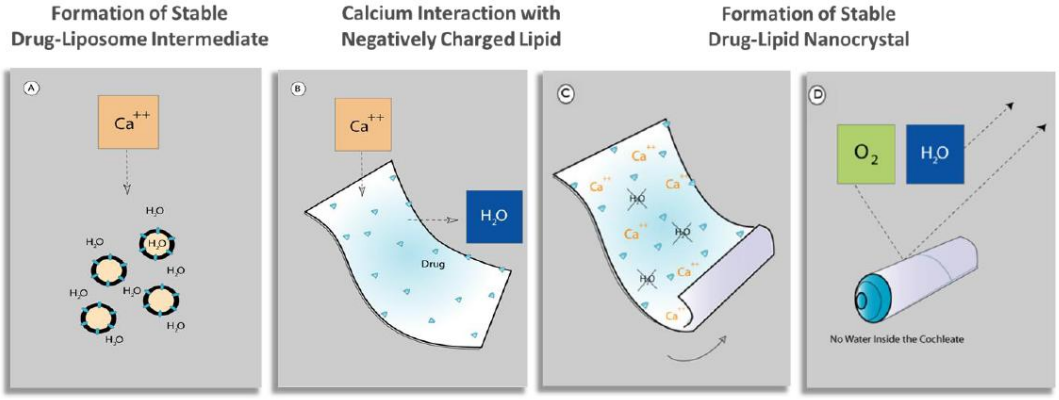
Figure 1: Current Delivery Technologies

	Liposome	LNP	AAV Viral Vector	LNC
				
Structure	• Aqueous interior surrounded by bilayer • Drug can be encapsulated in aqueous core or bilayer	• Ionizable lipid complexing with mRNA • Non-aqueous interior	• 26 nM Capsid housing <5 kb genome	• Non-aqueous bilayer • Highly stable • Much longer shelf life • Flexible structural design
Formulation goal	• Reduce Toxicity • Improve Bioavailability • Prolong half-life	• Intracellular delivery (ASOs, siRNAs, mRNA)	• Mostly target liver • Minimize empty vectors	• Hydophobic, water-insoluble drugs • Hydrophilic, water-soluble drugs • Control particle size • Further expand gene delivery • Significantly extend stability, shelf-life
Potential applications	• Hydrophilic and Lipophilic drugs	• mRNA, ASOs, siRNAs	• Gene therapy	• Large and small molecules • ASOs, mRNAs, siRNAs • Large nucleotides (up to 11 kB) • Proteins
Issues	• Leakage of encapsulated drug • Fusion • Limited shelf life	• Cationic lipid toxicity not suitable for chronic use • Anti-PEG allergic response • Very limited shelf stability • Cold-chain requirements	• Very high production cost • Viral genome integration • Package size < 4k BP • Re-treatment problematic • Immunogenicity	• Limited clinical experience to date

Our Solution: LNCs

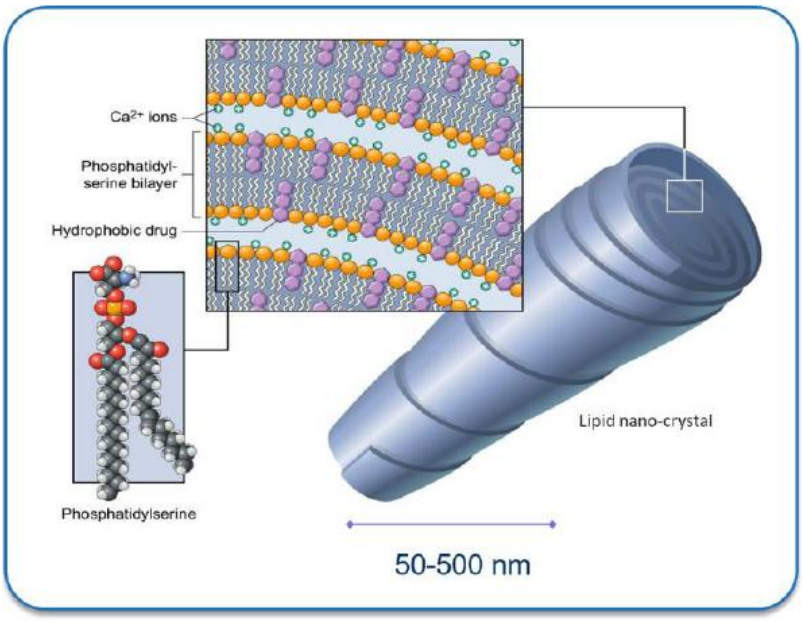
Our proprietary lipid nanocrystals (LNCs) are primarily composed of two naturally occurring materials: a phospholipid, like phosphatidylserine (PS), and calcium. They are stable and have a unique multilayered structure consisting of a large, continuous, solid, lipid bilayer sheet rolled up in a spiral or as stacked sheets, with no internal aqueous space. This unique structure provides protection from degradation for molecules trapped in or between lipid bilayers. Components within the interior of the LNCs remain intact, even though the outer layers of the LNCs may be exposed to harsh environmental conditions or enzymes (Figure 2).

Figure 2 LNC Formulation



Our LNCs protect active pharmaceutical ingredients in lipid bilayers and can intercalate into the phospholipid interior or otherwise remain trapped within the bilayers (Figure 3). The presence of minimal amounts of calcium keeps the LNCs intact.

Figure 3 LNCs Protect API in Bilayers



LNCs can be delivered in a variety of ways, including orally, intramuscularly, intravenously and through inhalation. This flexibility represents a significant advantage over other delivery modalities and presents significant opportunities to efficiently encapsulate many different molecules, both water soluble and water insoluble, including small molecules, nucleic acids such as antisense oligonucleotides (ASOs), messenger RNA (mRNA) and small interfering RNA (siRNA), and nucleotides as large as eleven kilobases including DNA plasmids and potentially CRISPR/Cas9, a gene editing technology.

Intracellular delivery of molecules is usually accomplished by either phagocytosis, clathrin-mediated endocytosis (CME) or through membrane fusion. LNPs are limited in that they can typically only access a cell through the CME process, followed by disruption of the endosomal membrane within the cell to gain access to the cytoplasm. LNPs typically are very inefficient, and patients also experience injection site adverse events and other toxicities associated with CME delivery, thereby limiting chronic use. LNPs also cannot be delivered orally. Viral vectors, including adeno-associated virus, attempts to utilize nature's intracellular delivery mechanisms to facilitate fusion with the cell membrane and delivery of molecules into a cell. Unfortunately, viral vectors have historically been associated with severe negative immune responses and, like LNPs, cannot be delivered orally. We believe LNCs can effectively delivery molecules through all three mechanisms, in addition to having great flexibility with the desired route of administration.

We believe that LNC's unique ability to enter a cell through phagocytosis, membrane fusion or CME, or a combination thereof, relates directly to the presence of a phospholipid, like phosphatidylserine. Phosphatidylserine (PS) is present in virtually all cells and is an integral part of the cell membrane. PS is normally localized to the inner part of the membrane bilayer by active cellular processes. However, with cell "activation", which occurs when there is infection, inflammation, injury, stimulation, cell death or some other issue impacting a particular cell, PS moves from the inner layer to the outer layer and facilitates fusion with our LNCs (Figure 4). Certain cells also contain PS receptors, which actively take up LNCs due to the presence of PS (Figure 5).

Figure 4: Asymmetry of the Phospholipid Membrane

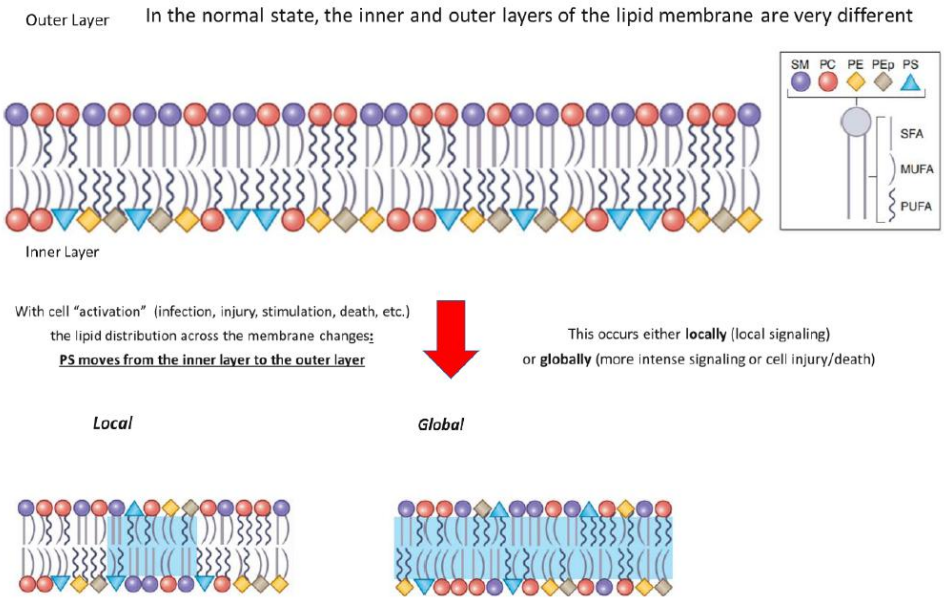
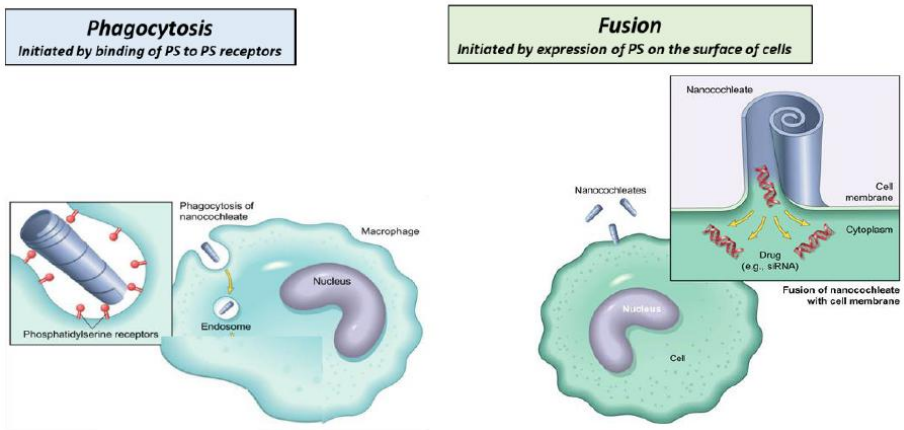


Figure 5: Role of PS and PS Receptors in the Uptake of LNCs into Cells



Through phagocytosis, macrophage and other cells containing PS receptors readily engulf LNCs and their drug cargo into vesicles, or endosomes, facilitating intracellular delivery. LNCs can also fuse with cell membranes and deliver drug cargo directly to the cytoplasm. LNCs have been designed to mimic enveloped viruses and can efficiently deliver drugs and/or molecules to cells without adverse immune responses.

For some molecules, the goal is simply to achieve safe and effective intracellular delivery. This is especially relevant when delivering sensitive genetic material and other molecules desiring cellular impact (i.e., antivirals). For other molecules, or drugs, utilizing activated cells as a mechanism to deliver drug to infected tissues or other areas of the body becomes critical.

LNCs in pre-clinical studies have been shown to improve existing drugs by providing 1) cell-targeted delivery; 2) reduced blood levels thereby reducing toxicity; and 3) oral delivery of drugs now only available intravenously. For example, LNCs delivered orally work by encapsulating molecules of drugs in a solid, anhydrous, crystalline structure, protecting them as they pass through the GI tract where they cross the mucous membrane. Once the LNCs have crossed the mucosal barrier of the GI tract into the lymphatic system, they are picked up by activated cells including cells of the mononuclear phagocytic system, such as macrophages and dendritic cells. Activated macrophages, with drug-loaded LNCs inside, follow natural signal molecule paths and migrate to the site of infection or to the target organ and deliver their payload.

Therapeutic applications of our proprietary delivery technology have been initially focused on the delivery of several potent and highly efficacious anti-fungal and anti-bacterial agents, which are currently still associated with serious side effects, including irreversible toxic effects on kidney and hearing function. We believe our technology has the potential for targeted delivery of these agents, which positions us to be at the forefront of dealing with these very serious problems. We have now also expanded our research and development efforts for our LNC platform delivery technology to focus on the delivery of a wide range of therapeutic treatments, in particular those in the oligonucleotide class of agents (antisense oligonucleotides, mRNA, and CRISPR-Cas9).We continue to push forward our business development efforts to further expand our collaborations across pharma and biotech companies who have innovative therapies with delivery challenges, which may be addressed with our LNC platform delivery technology.

Multi-organ Protection: A key innovation of our LNC platform delivery technology is our ability to package medication inside lipid-crystal particles without leaking. Because of their crystalline nature, these particles are truly solid and hold on tightly to their medication payload. This is where the LNC platform delivery technology differs markedly from other lipid-based delivery technology, such as liposomal delivery. Liposomes are liquid delivery systems which typically leak some of their drug content into the circulatory system, thus still exposing vulnerable organs and tissues to potential toxic effects. Keeping potentially organ-toxic medications inside the lipid-crystal particles significantly differentiates our LNC platform delivery technology from other drug-delivery approaches.

Targeted Delivery: The size of our individual LNCs is typically in the range of 50-500 nm. This is very small and by comparison close to the size of a large virus or a small bacterium. Our body produces many activated cell-types that are predisposed to interact with our LNCs. These activated cell types, including bone marrow-derived hematopoietic cells such as macrophages, infected cells, injured cells, tumor cells and epithelial cells are all prone to engulf or fuse with our phosphatidylserine-based LNCs. Because of the size of our LNCs and their PS surface structure (the cell membranes of bacteria are also made up from PS), activated cells tend to take up these LNCs very efficiently and without any adverse immune response.

Oral Formulation: Many drugs that are currently on the market are only effective in treating diseases when administered intravenously. For example, many anti-infective drugs must be administered intravenously in order to be effective. IV administration presents several challenges to care, such as risk of infection, patient discomfort from injections, and higher cost of care than anti-infective drugs that can be taken orally (IV delivery must be performed by a doctor or nurse, often within a very expensive hospital setting). Although several technologies have been used to attempt to convert IV drugs to orally delivered medications, success has been limited due to the difficulty in achieving adequate bioavailability (i.e., the amount of drug that is absorbed into the body) with an oral formulation. We believe that the unique LNC structure in our platform technology protects the drug from degradation when it passes through the GI tract and that its lipid surface features facilitate the particle being absorbed into the blood stream. The potential application of our LNC platform delivery technology for the delivery of injectable medications offers significant clinical and commercial value with successfully demonstrated safety and efficacy in human clinical trials.

Our LNC platform technology changes the delivery of medicines in a unique manner and alters the bio-distribution of these medications by targeting tissues and organs that are affected by infection and inflammation. In addition to IV-only anti-infectives such as amphotericin B and amikacin, we have orally delivered in animal studies the influenza vaccine, siRNA, NSAIDs, other anti-infectives such as atovaquone, and many other compounds across multiple therapeutic areas, demonstrating the potential broad application of our technology. We have observed rapid local accumulation in infected tissues, which appear to be the result of transport of our drug-loaded LNCs by and to activated cells.

Our LNC Clinical Stage Assets

We have leveraged our platform LNC delivery technology to develop two clinical-stage products that we believe have the potential to become best-in-class drugs in their respective therapeutic classes. Our lead LNC platform delivery technology product candidate, MAT2203, is an orally-administered LNC formulation of a broad spectrum anti-fungal drug called amphotericin B. We believe there are opportunities for a potentially rapid approval of MAT2203 for the treatment of certain invasive fungal infections in areas of high unmet medical need. In partnership with the National Institutes of Health (NIH), we have conducted numerous preclinical studies of MAT2203 for the treatment of cryptococcal meningitis (CM), a deadly fungal infection that affects the brain, typically in immunocompromised individuals. In such studies, we observed the potential for MAT2203, utilizing our LNC platform delivery technology, to (a) cross the blood-brain barrier, (b) treat this infection and (c) eliminate the toxicity normally associated with intravenous delivery of amphotericin B.

Based upon the preclinical data generated by the NIH, the NIH has financially supported a grant application from the University of Minnesota to conduct the EnACT study in Uganda. This study was initiated in October 2019 and is exploring the use of MAT2203 for both induction and maintenance therapy in the treatment of CM, which is one of the most frequent and opportunistic infections in HIV patients. Given the high morbidity and mortality associated with CM in HIV patients, the clinical unmet need is globally very high with the global burden estimated at 1 million cases annually. We plan to leverage a 505(b)(2) regulatory pathway for MAT2203, in part relying upon FDA's findings of the efficacy of IV amphotericin B. This strategy was discussed with the FDA in June 2019, where we outlined our development plans for MAT2203 in CM and received FDA approval to proceed with the EnACT study which is currently enrolling subjects in Cohort 2 of the trial. We have received four qualified infectious disease (QIDP) designations as well as an orphan designation for the treatment of cryptococcosis, which, if approved, would result in twelve years of regulatory exclusivity for MAT2203. We plan to seek accelerated approval for this indication following the availability of the results of the ongoing EnACT Study. We believe that this study may have the potential to become a potential pivotal study to support approval of MAT2203 for the treatment of CM during both induction and maintenance phases of treatment.

Our second clinical stage LNC-based product candidate is MAT2501, an orally administered formulation of the broad-spectrum aminoglycoside antibiotic amikacin, which may be used to treat different types of multidrug-resistant bacteria, including non-tuberculous mycobacterium infections (NTM), as well as various multidrug-resistant gram negative and intracellular bacterial infections. In May 2017, we completed and announced topline results from a Phase 1 single escalating dose clinical trial of MAT2501 in healthy volunteers in which no serious adverse events were reported and where oral administration of MAT2501 at all tested doses yielded blood levels that were well below the safety levels recommended for injected amikacin, supporting further development of MAT2501 for the treatment of NTM infections. Following reformulation work, in 2019, we received a grant from the Cystic Fibrosis Foundation (CFF) to complete preclinical studies with Colorado State University which further demonstrated the potential for MAT2501 in treating cystic fibrosis-associated NTM lung infections. In November 2020, we received an additional grant from the CFF in the amount of 3.75 million USD to support the continued development of MAT2501 through a comprehensive preclinical tox program and a single ascending dose (SAD) study in healthy volunteers with our new and improved formulation of MAT2501. This most recent grant was based upon the positive preclinical proof of concept data generated by Dr. Diane Ordway at Colorado State University in a rigorous mouse model of NTM infection in mice with underlying CF disease.

MAT2203

Our lead anti-fungal product candidate, MAT2203, is an application of our LNC platform delivery technology to a broad spectrum and potent anti-fungal drug called amphotericin B. Traditionally, amphotericin B is an IV-administered drug used as a last resort for treatment of systemic fungal infections resistant to triazoles and echinocandins, including resistant candidiasis, cryptococcal meningoencephalitis, and aspergillosis. To date, there have been little to no reports of clinically observed drug-resistance to amphotericin B, further bolstering the use of this compound as the most likely last resort treatment for fungal infections in the foreseeable future. However, the use of amphotericin B is relatively limited because it is currently only available as an IV-administered product and has documented history of severe toxicity (most notably

nephrotoxicity). By utilizing our LNC platform delivery technology to nano-encapsulate amphotericin B, there is now an opportunity for the drug to be administered orally with targeted delivery to infected cells, which we believe may have fewer side effects than the currently available IV-formulations of amphotericin B. Our LNC delivery of amphotericin B changes the bio-distribution, resulting in a higher level of the drug at the site of infection and a lower level of free circulating amphotericin B. By reducing the amount of circulating drug, our LNC platform delivery technology may reduce overall toxicity. Importantly, drug concentrations will be high only in target tissues due to the migratory nature of activated cells to inflammatory regions. Based upon our studies to date, we believe MAT2203 has the potential to offer improved safety and reduced toxicity and, as a result, we believe MAT2203 will be able to offer a categorically different and improved formulation that delivers orally administered amphotericin B, directly to the target cell at the site of infection. In collaboration with the NIH, in multiple studies, we have demonstrated in CM mouse models that our LNC-delivered amphotericin B, following oral administration, can successfully cross the blood brain barrier to the site of infection in mice. This demonstration provides important data indicating that our LNC platform delivery technology could become an important delivery solution for a variety of CNS-based disorders and diseases.

We believe that MAT2203 has the potential to become a best-in-class induction, consolidation, and maintenance therapy for the treatment of CM in HIV patients by offering the following key benefits:

- **Potential to treat resistant pathogens**. We believe that MAT2203 has the potential to prevent and treat fungal infections caused by drug-resistant fungi, including those resistant to existing azoles and echinocandins, due to amphotericin B's fungicidal (i.e., killing the fungi) nature and potency against resistant strains and the potential for our LNC platform delivery technology to provide higher drug exposure early in the course of therapy.

- **Enabling an all-oral therapy.** CM has become the most common cause of adult meningitis in many parts of Africa, where cryptococcosis now rivals tuberculosis in all-cause mortality. While long-term survival has improved with widespread use of antiretroviral therapy in high-income countries, early mortality remains high. Early mortality rates are often ~ 70% in routine practice where access to diagnostics or medications is limited or unavailable, intracranial pressure is uncontrolled, or in settings where other barriers to the management of CM exist. IV administration of amphotericin B deoxycholate is not often possible in resource-limited settings, even when it is available.

- **Shorter and less costly hospital stays and lower outpatient costs**. By providing physicians and patients with access to an orally available, broad spectrum fungicidal agent in MAT2203, there is the potential to reduce hospital costs, which account for over 70% of the overall treatment cost of invasive fungal infections.

The FDA has granted MAT2203 designations for Qualified Infectious Disease Product, or QIDP, and Fast Track for the treatment of invasive candidiasis and aspergillosis, for the prevention of invasive fungal infections in patients on immunosuppressive therapy, and the treatment of cryptococcosis. We recently also received Orphan Drug Designation for MAT2203 for the treatment of cryptococcosis and associated CM. The FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. The orphan drug designation provides eligibility for orphan drug exclusivity in the United States upon FDA approval if a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation. For a product that obtains orphan drug designation based on a plausible hypothesis that it is clinically superior to the same drug that is already approved for the same indication, in order to obtain orphan drug exclusivity upon approval, clinical superiority of such product to this same drug that is already approved for the same orphan indication must be demonstrated. Orphan drug exclusivity means that the FDA may not approve any other applications, including an NDA, to market the same drug for the same indication for seven years, except in limited circumstances such as 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. Similarly, the FDA can subsequently approve a drug with the same active moiety for the same condition during the exclusivity period if the FDA concludes that the later drug is clinically superior, meaning the later drug is safer, more effective or makes a major contribution to patient care. Orphan drug designation also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, a waiver from payment of user fees, an exemption from performing clinical studies in pediatric patients unless the FDA requires otherwise by regulation, and tax credits for the cost of the clinical research. The QIDP designation, provided under the Generating Antibiotic Incentives Now Act, or the GAIN Act, offers certain incentives for the development of new antibacterial or antifungal drugs, including eligibility for Fast Track designation, priority review and, if approved by the FDA, eligibility for an additional five years of marketing exclusivity. Fast Track designation enables more frequent interactions with FDA to expedite drug development and review. Fast Track designation does not change the standards for approval, and we can provide no assurances that we can maintain Fast Track designation for MAT2203 or that such designation will result in faster regulatory review. The seven-year period of marketing exclusivity provided through orphan designation, if granted, combined with an additional five years of marketing exclusivity provided by the QIDP designation positions MAT2203 with a potential for a total of 12 years of marketing exclusivity to be granted at the time of FDA approval.

MAT2203 - ***Product Profile***

MAT2203 is an orally-administered, LNC formulation of amphotericin B (a broad-spectrum fungicidal agent). Little to no clinical resistance has been reported to date with amphotericin B as compared to the rapidly emerging drug resistance seen with other antifungal therapies. Currently, IV administered amphotericin B is the only broad spectrum fungicidal; however, it has significant treatment-limiting side effects, most notably nephrotoxicity. We believe that the ability to provide amphotericin B orally using our proprietary and novel oral formulation comprising our LNC platform delivery technology, may offer a new and promising alternative for patients and doctors.

The data from animal toxicity studies for MAT2203 indicate a side-effect advantage over other amphotericin B formulations, which we believe is based on two phenomena:

- The lipid- nanocrystal is a solid particle that does not significantly "leak" its drug content while circulating. The particle releases its medication pay-load only when inside the target cells, and thus appears that the use of MAT2203 does not result in off-organ toxicities normally seen in the kidneys when using current formulations of amphotericin B.

- Because of this targeted approach, we have been able to increase the therapeutic window on a mg/kg basis as compared to IV amphotericin B formulations. We have observed equivalent efficacy at lower doses as well as been able to use oral doses of up to 10x the highest tolerable IV dose in animal model studies.

Development History of MAT2203 and Initial Target Indication

MAT2203 has been studied extensively in animal model studies of various fungal infections including invasive candidiasis, aspergillosis, and CM.

In a clinical Phase 1 single-dose, double-blind, dose-escalating, pharmacokinetic study of 48 healthy volunteers, oral MAT2203 was observed to be well-tolerated with no serious adverse events reported, and without any observed nephrotoxicity. The most commonly reported adverse events (AEs) were nausea and abdominal pain. None of the AEs were related to abnormal laboratory evaluations. All treatment emergent adverse events (TEAEs) were mild except 1 instance of "upper respiratory tract infection" which was moderate in a subject following 800 mg MAT2203. No AEs led to withdrawal. There were no serious AEs. There was one pregnancy (subsequently determined that the conception date was 1 to 2 days prior to dosing) resulting in elective termination from the study. More recently, in our Phase 2 trial of MAT2203 conducted by the NIH, four out of four enrolled patients suffering from chronic refractory mucocutaneous candidiasis met their primary efficacy endpoint. One patient continues on treatment with no evidence of kidney or other toxicity frequently associated with the use of amphotericin B.

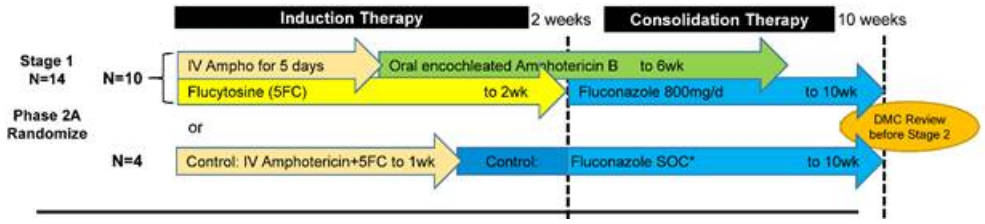
In October 2020, results from Phase 1 of the EnACT Study were published in the Journal of Antimicrobial Agents and Chemotherapy (C. Skipper, et.al) which was a Phase 1

ascending-dose trial of MAT2203 administered at 1.0 g, 1.5 g, or 2.0 g per day in 4 to 6 divided doses among HIV-positive survivors of cryptococcosis (n=9 per cohort). We assessed the tolerability of MAT2203, and the AEs associated with MAT2203 treatment over three days. The second part of the Phase 1 trial assessed the tolerability of 1.5 grams/day (the 100% tolerated dose) administered for seven days. In the singe-ascending dose part of the study, all subjects in the 1.5 g treatment group received their full dose without vomiting (100% tolerability). The cohort receiving 1 g had 4 transient clinical AEs in 2 subjects. The cohort receiving 1.5 g had 7 clinical AEs in 1 subject. The cohort receiving 2 g had 20 clinical AEs in 5 subjects. From a qualitative survey, 26 of 27 (96%) preferred their experience with MAT2203 over their prior experience with IV amphotericin (AMB).

The second, multiple dose cohort received 1.5 g/day for 1 week, which was the 100% tolerated dose, with 98.4% of doses taken. Overall, 5 clinical AEs occurred in this cohort of subjects without any observed kidney toxicity. Oral MAT2203 was well-tolerated when given in 4 to 6 divided daily doses without the toxicities commonly seen with IV AMB.

Based on the findings from Phase 1 of the EnACT Trial, 2.0 g was selected as the target dose for the induction phase of treatment and 1.5 g for the maintenance dose for Stage 1 of the study. Phase 2 of the trial is evaluating the safety, tolerability, and efficacy of MAT2203 in approximately 100 HIV-infected patients with cryptococcal meningitis. Participants enrolled in the experimental arm of each cohort received oral MAT2203 and flucytosine (5FC) in four separate stages and duration for induction therapy, using the maximum tolerated dose of MAT2203 that was identified in the preceding Phase 1 Trial. The experimental arm receives MAT2203 through induction and maintenance therapy for a total of approximately 6 weeks. Participants randomized to the control arm in each cohort receive the 2018 WHO recommended standard of care, which is IV AMB and 5FC, followed by fluconazole.

The first cohort of EnACT has been completed. A key objective of Cohort 1 was to assess the safety and tolerability of oral MAT2203 while assessing efficacy. Ten participants were randomized to the experimental arm and 4 to the control arm. The study treatments received are summarized in the following figure:



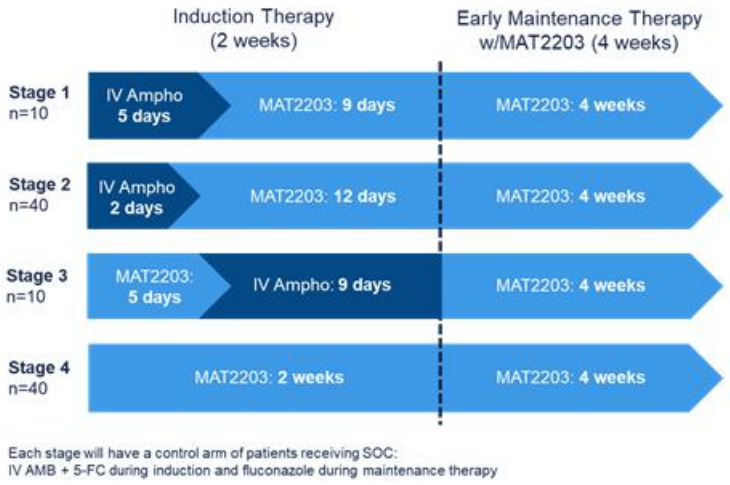
Patients in the experimental arm received induction therapy with IV AMB (1 mg/kg/day) for the first five days, oral MAT2203 (2 g/day in divided doses) from Day 5-14, and oral 5FC (100 mg/kg/day) for the first 14 days of treatment. Induction therapy was followed by consolidation or maintenance therapy with oral MAT2203 (1.5 g/day) from Day 15 to Week 6, oral fluconazole (800 mg/day) from Day 15 to week 10, followed by oral fluconazole (200 mg/day).

Efficacy and safety data from Cohort 1 of the study were reviewed by an Independent Data Safety Monitoring Board (DSMB) which voted unanimously to progress into the second cohort of patients in the EnACT Study.

Enrollment in the second cohort of patients has begun and Cohort 2.

Cohort 2 (or Stage 2) of the EnACT Study is designed to assess the potential to treat CM infections with oral MAT2203 as a step-down treatment during the induction phase of treatment immediately following only 2 days of IV amphotericin treatment, with continued treatment with MAT2203 for up to 6 weeks during early maintenance treatment. We believe that the clinical benefit of step-down treatment from IV amphotericin to oral MAT2203 will provide compelling clinical evidence of efficacy in treating this deadly infection with our oral agent. We believe that this Cohort of patients will also provide key data to support the further advancement of the EnACT Study to ultimately test the potential to treat CM infections with an all-oral amphotericin dosing regimen in subsequent cohorts (Stages 3 and 4 below).

The read-out for Cohort 2 is expected in the second half of 2021.



Antifungal Market Opportunity

The overall global antifungal market accounted for approximately $11.9 billion in 2018 and is expected to reach approximately $13.9 billion by 2026. In 2018, the global invasive fungal infection market was valued at more than $6 billion. This includes therapies used as active treatment or prophylaxis (preventative) in the inpatient and outpatient setting, therapies used for the treatment of hospitalized patients and therapies used for the treatment of patients who are being discharged from the hospital. We estimate that, each year, there are over 1.5 million cases of invasive fungal infections caused by various species of *Candida, Aspergillus* and *Cryptococcus,* the three most common invasive fungal pathogens, globally. The estimated incidence in the U.S. for these conditions is approximately 46,000 for invasive candidiasis, 15,000 for invasive aspergillosis, and 3,700 for CM. For example, aspergillosis-associated hospitalizations in the U.S. alone came at an estimated treatment cost of more than $1 billion. The rapid progression of disease and high mortality rates (20% - 50%) associated with documented invasive fungal infections often result in antifungal therapy being administered in suspected (unconfirmed) cases or as a preventative measure in patients at high risk. Also, the increasingly widespread use of immune suppressive drugs as cancer chemotherapy or for organ transplantation or treatment of autoimmune disease has resulted in an increasing population of patients at risk for invasive fungal infections. Furthermore, the limited

number of systemic antifungal drug classes, consisting of azoles, echinocandins and polyenes, and their extensive use, has led to increased numbers of infections with drug-resistant strains. The Centers for Disease Control and Prevention (CDC) has listed fluconazole-resistant *Candida* as a serious threat requiring prompt and sustained action and has also identified a rise in echinocandin resistance, especially among *Candida glabrata.* In June 2016, the CDC issued an extraordinary alert for healthcare facilities and providers to be on the lookout for patients with *Candida auris*, a multidrug resistant strain with high mortality (approximately 60%). Almost half of*C. auris* isolates are multidrug resistant to two or more antifungal classes (large majority resistant to fluconazole, 40% resistant to echinocandins). We believe this underscores the urgent need for new agents with demonstrated activity against resistant strains and that can be administered with significantly less toxicity and the potential to discharge patients earlier to reduce hospital stays and associated costs.

Physicians' options for the treatment of fungal infections are limited by a lack of innovative therapies. Several factors have contributed to the low rate of antifungal drug development, including a previously challenging regulatory environment that necessitated large and costly clinical trials. As a result of this regulatory environment and other factors, the number of antifungals in development has decreased, while anti-microbial resistance has increased.

MAT2501

MAT2501 is an oral, LNC formulation of the broad-spectrum aminoglycoside antibiotic agent amikacin, which utilizes our proprietary LNC platform to achieve oral bioavailability, limit toxicity, and enable targeted delivery to sites of infection. Currently, amikacin can only be delivered parenterally or through inhalation and is used to treat a variety of chronic and acute bacterial infections, including both NTM infections and various multi-drug resistant gram-negative bacterial infections. IV and inhaled amikacin, however, are associated with major side-effects including nephrotoxicity and ototoxicity (permanent loss of hearing) with long-term use. We believe that MAT2501's ability to orally deliver high levels of amikacin directly to the lung and without use-limiting toxicity, distinguishes it from all available therapies and could provide an important solution for patients and physicians. We are currently developing MAT2501 for the treatment of NTM lung disease, including infections in patients with CF. MAT2501 has been designated as a Qualified Infectious Disease Product (QIDP) and as an Orphan Drug for the treatment of NTM by the US FDA.

NTM lung disease is a chronic, debilitating condition arising from an NTM infection in the lungs and is associated with significant patient morbidity and mortality. The signs and symptoms of NTM lung disease often overlap with the underlying lung conditions that increase the risk for NTM, like cystic fibrosis, bronchiectasis, COPD, and asthma. The most common pathogens for NTM infections in the United States are *Mycobacterium avium complex* (MAC), which accounts for more than 80% of all NTM infections in the US. Patients with NTM lung infections frequently require lengthy hospital stays and prolonged courses of antibiotics to manage their disease. The prevalence of human disease attributable to NTM has increased over the past two decades and is now growing at more than 8% per year and is even more prevalent than tuberculosis in the US. In 2018, it was estimated that between 75,000 and 100,000 patients were diagnosed with NTM lung disease in the US alone.

Non-tuberculous mycobacterium (NTM) infections are extremely difficult to treat, especially so in patients with cystic fibrosis (Eikani,*et. al*., 2018). The infecting organisms are frequently resistant to most antibiotics, and current treatment regimens require combination therapies with highly toxic drugs for long periods of time, further complicated by challenges in delivering therapeutic levels of these toxic drugs across plasma membranes of infected cells.

These challenges are amplified in CF patients, with the thick buildup of pulmonary secretions that further impair treatment of infecting organisms. Pulmonary infections represent the most frequent type of infection in CF patients, and are responsible for more than 90% of deaths in the CF population (Rowe SM, *et.al*. 2005). Mycobacterium avium complex (MAC) and Mycobacterium abscessus complex (MABSC) are non-tuberculous mycobacterial species that have emerged in recent years as important opportunistic pathogens frequently responsible for pulmonary infections in CF patients (Brode SK, *et. al*. 2014). Infections due to MAC and MABSC are difficult to treat and to eradicate since these organisms are naturally resistant to most antibiotics. The recommended treatment for MAC and MABSC pulmonary infections includes a combination of a macrolide (clarithromycin or azithromycin), an aminoglycoside (amikacin), and an antimycobacterial antibiotic for MAC (rifampin and ethambutol), while MABSC many times requires intravenous β-lactam (cefoxitin or imipenem) at least for 12 months (Floto RA, *et. al.*, 2016). The cure rate is only 25-40% in the case of macrolide resistance, which is present in 40 to 60% of the isolates (Roux AL *et. al*., 2015). Moreover, unsuccessful eradication of MAC and MABSC is considered as a contraindication for lung transplantation by several CF centers, and significantly restrict therapeutic options in severely ill patients. Therefore, more specific and active and less toxic antimicrobials are urgently needed.

MAT2501 Previous and Ongoing Studies

The most recent completed pre-clinical animal model studies testing the preclinical efficacy of MAT2501 were funded by a grant from the Cystic Fibrosis Foundation (CFF). An additional grant was awarded from the CFF in February of 2020 to support the screening of new optimized formulations of MAT2501 in collaboration with Diane Ordway, Ph.D. of Colorado State University (CSU). Most recently, a CFF grant of $3.75 million was awarded to us in November 2020 to support the early development of MAT2501 through the end of Phase 1. The recent grant from the CF Foundation was based upon the data generated by CSU and summarized below.

Preclinical and Clinical Studies

The Investigational New Drug (IND) application for MAT2501, was opened in January 2016 to investigate MAT2501 in the proposed indication for treatment of non-tuberculosis mycobacterial (NTM) infections.

We have conducted numerous repeat-dose non-clinical studies including a 28-Day rat study and 3 nonclinical studies in large animals (2 with dog and 1 with dog and minipig). Data generated to date suggest no toxicity signals related to those observed with IV amikacin.

We have conducted to date a first-in-human Phase I study entitled: A Phase 1, Double-Blind, Placebo- Controlled, Single, Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Encochleated Amikacin (CAMK/MAT2501) Following Oral Administration in Healthy Adult Subjects. Safety was monitored through physical examinations, vital signs, 12-lead ECGs, audiometry tests, pupillary reflex tests and clinical lab tests. No serious adverse events were reported in the study. Adverse events were tolerable and not unexpected. There were no adverse events related to audiology assessments or ophthalmic pupillary reflex testing. A total of 36 subjects were entered into this study in three (3) cohorts (dosing of 12 subjects (9 active drug subjects and 3 placebo subjects in each cohort). Doses tested were 200mg under fasted conditions, 400mg under fasted and fed conditions and 800mg under fed conditions. One subject in high dose cohort (800 mg dose, fed condition) was discontinued early during the study as a result of gastrointestinal issues possibly related to study drug. The study was completed in March of 2017 and the final clinical study report was submitted to the IND in February of 2018.

MAT2501 (LNC Oral Amikacin) for the Treatment of NTM Infections in Mouse Models of CF

***In vivo* chronic efficacy studies**

MAT2501 was tested in *in vivo* experiments of NTM infections in CF mouse models. In the CF ($B6CFTR^{tm1UNC}/CFTR^{tm1UNC}$) mice chronic model for CF, the CAMK was administered daily for each NTM species tested on each of the six NTM strains across two tiers. Tier 1 included strains having a low drug resistance and Tier 2 included drugs that were resistant to macrolide antibiotics (See Table 1).

Table 1. US Clinical Isolates

Tier 1 (low drug resistance)	Tier 2 (macrolide resistant)
M. avium ssp. intracellulare	*M. avium subsp intracellulare*
M. abscessus ssp. massiliense	*M. abscesus ssp abscessus*
M. avium ssp. hominissuis	*M. abscessus ssp bolletii*

Study Design

Six CF chronic model experiments were conducted i) to evaluate whole organ bacterial burden and ii) to evaluate whole organ pathology and metabolic stability using hepatocytes from mice. Groups of CF mice were infected with mycobacterium avium (Ma) and mycobacterium abscessus (Mabs) strains as described in Table 1. On day 2 after infection, 5 mice in each group were ethically euthanized to quantify the initial bacterial burden. Treatment for the remaining animals began after 28 days of infection. Oral MAT2501 100 mg/kg QD, Oral MAT2501 100 mg/kg BID, untreated control and two positive controls (oral clarithromycin 250 mg/kg and subcutaneous amikacin 150 mg/kg 3x/week) were administered for 8 weeks. After the drug treatment began, any effect the compound had on lung, liver and spleen bacterial numbers and organ histology was assessed (CFU, pathology) at intermittent time intervals of treatment (2, 4, 8, weeks of drug treatment) and compared to untreated concurrent control saline and clarithromycin 250 mg/kg and amikacin 150 mg/kg control values (Obregon A., *et. al*, 2015).

Conclusions

Oral administration of MAT2501 safely and effectively treated Mycobacteria infections in a mouse model of Cystic Fibrosis.

- Colony counts showed that the oral administration of MAT2501 100 mg/kg resulted in CFU lung, spleen and liver counts that were lower than those in mice receiving parenteral amikacin alone.
- Colony counts showed that the oral administration BID of MAT2501 resulted in CFU lung, spleen and liver counts that were significantly lower than those in mice receiving clarithromycin alone.
- The lung pathology in cystic fibrosis mice infected with each of the NTM isolates evaluated in this study showed that lesions were more numerous and larger in infected mice that were treated with clarithromycin or parenteral amikacin compared to the smaller lesions after oral administration of MAT2501.

NTM Treatment Guidelines and Limitations of Current Treatments

The American Thoracic Society (ATS), European Respiratory Society (ERS), European Society of Clinical Microbiology and Infectious Diseases (ESCMIID), and Infectious Diseases Society of America (IDSA) jointly sponsored the recent development of updated NTM Treatment Guidelines in adults (Daley C, *et.al*, 2020). The guidelines recommend a standard NTM lung disease treatment with a combination of 3-4 medications. These include Amikacin (or streptomycin), clarithromycin (or azithromycin), rifampin (or rifabutin), and ethambutol. Amikacin is an important drug used for treatment of *Mycobacterium abscessus* pulmonary disease. Certain combinations of antibiotics work better together because of their unique mechanisms of action that work in concert to eliminate the infection. It is for this reason that sputum samples are qualified for precise identification of the species and sensitivity testing of the microorganism. When treatment failures arise, another combination of antibiotics will be recommended depending on the NTM strain.

Multiple drug therapy in NTM lung disease can cause adverse effects, which leads to treatment discontinuation or patient nonadherence. Current guidelines recommend monitoring for drug toxicity at repeat intervals. Gastrointestinal side effects with oral agents are common. Due to severe gastrointestinal disturbance, the use of macrolides may require dose adjustment. Drug-induced hepatotoxicity due to rifampin and other agents must be monitored by liver function tests and monitoring complete blood count when using rifampin or tigecycline is recommended. Renal function testing is required with IV amikacin use due to its known renal toxicity liability, an issue that we believe could be addressed with our novel targeted LNC oral formulation of amikacin, MAT2501. Due to the established risk of otoxicity such as hearing loss, tinnitus, or vestibular toxicity, patients who receive IV amikacin or streptomycin need to be educated regarding the signs and symptoms of toxicity with audiometry testing at the start of therapy and again on subsequent visits with discontinuation, or a decrease in dose or frequency if signs suggestive of toxicity occur. There remains a significant unmet clinical need for safer, yet potent, agents for the improved management of NTM lung disease. MAT2501 has the potential of providing a safer and more targeted approach to the treatment of NTM disease.

The early development plan for MAT2501 builds upon the preclinical proof of concept*in vitro* studies which have demonstrated antibiotic activity against both sensitive and multidrug resistant strains *M. abscessus and M avium.* The planned Tox Program will evaluate the optimized formulation of MAT2501 in a rigorous battery of studies to assess and characterize the safety profile of MAT2501. The planned studies will support the safety package required to progress the development of MAT2501 into Phase 2 clinical trials. These studies will carefully monitor the safety signals known to be associated with IV amikacin treatment (hearing loss and kidney/renal safety). These studies will include:

- 28 rat toxicity study to assess any potential effects of MAT2501 on hearing and associated side effects
- 3- and 9-month long-term safety study in dog to support longer-term dosing in clinical trials

These GLP studies are planned to be initiated in the second half of 2021 and will commence following FDA review of the protocols for the 3- and 9-month dog study, which will be submitted for review by Q3 2021.

A Phase 1 SAD Study will also be conducted with the optimized formulation in parallel with the long-term tox study and is expected to be initiated in Q4 2021 with final data available early 2022.

LYPDISO

Overview

LYPDISO is a complex mixture of multiple long-chain omega-3 fatty acids, primarily eicosapentanoic acid (EPA) and docosapentanoic acid (DPA) encapsulated in a delayed release soft gelatin capsule. Unlike currently approved pharmaceutical omega-3 products, all of which have been repurposed following clinical failures in their originally intended indications, LYPDISO has been specifically designed and developed to treat HTG in patients with cardiovascular and metabolic conditions. There are a number of existing FDA-approved omega-3 products, including Lovaza®, Vascepa® and Epanova®, and this class of drugs has extensive evidence of safety and well-documented clinical efficacy in lowering TGs in patients with HTG. Vascepa has also demonstrated the ability to achieve meaningful reductions in cardiovascular risk based primarily upon achievement of elevated levels of EPA in the blood. We believe that given LYPDISO's enhanced bioavailability (as a free fatty acid rather than an ethyl ester) and its unique composition (high EPA plus DPA), it can be differentiated from other existing products in the omega-3 class and have uniquely potent impacts on TGs, but also a variety of other biomarkers, including achieving elevated levels of EPA in the blood.

Currently, the only available route to an approval for TG-lowering with a prescription omega-3 drug is in severe hypertriglyceridemia (SHTG), where patients have TG levels ≥ 500 mg/dL, and where TG-lowering is a well-accepted surrogate marker. Additionally, Vascepa has been approved for cardiovascular risk reduction in patients at high

cardiovascular risk with TGs ≥ 150mg/dL, based upon its ability to achieve elevated levels of EPA in the blood. Our current development plan is via a 505(b)(2) regulatory pathway, which allows us to rely, at least in part, on FDA findings of safety and/or effectiveness for a previously approved drug. Based on prior written feedback received from the FDA in 2014, and additional verbal and written feedback from FDA in August of 2020, we believe that a 505(b)(2) pathway is possible and appropriate for LYPDISO.

In parallel with the preclinical and clinical studies necessary for FDA approval of LYPDISO, we also recently completed the ENHANCE-IT study, a head-to-head crossover study of LYPDISO vs. Vascepa, which was intended to differentiate LYPDISO from the current leading prescription omega-3 therapy. We believe that the results from ENHANCE-IT suggest potential for LYPDISO as a best-in-class prescription omega-3 for cardiovascular risk reduction and we are pursuing a partnership to continue development of LYPDISO moving forward. We do not plan on pursuing an indication for SHTG and have reallocated resources away from this clinical indication.

Hypertriglyceridemia and Cardiovascular Disease

Triglycerides and cholesterol are integral components of lipoproteins, the primary transport vehicle for lipids in the body. High levels of triglyceride-rich lipoproteins are associated with a substantially increased risk of atherosclerotic cardiovascular disease, and in the case of very high triglycerides (> 500 mg/dL), acute pancreatitis. HTG can be due to both genetic and environmental factors, including obesity, a sedentary lifestyle, and high caloric diets. HTG is also tightly linked with comorbid conditions such as diabetes, chronic renal failure, and nephrotic syndrome. It is estimated that over 25 million adults in the United States have triglyceride levels ≥200 mg/dL and that more than 50 million adults in the United States have triglyceride levels ≥150 mg/dL. Additionally, approximately 4 million adults in the United States have very high triglyceride levels (≥500 mg/dL). The prevalence of HTG is rapidly increasing in both the United States and throughout the world, as a direct consequence the growing epidemic of obesity. Recent studies have confirmed that high levels of triglyceride-rich lipoproteins are an independent risk factor for cardiovascular disease-related events such as myocardial infarction, ischemic heart disease, and ischemic stroke. Mixed dyslipidemia refers to a condition in which patients have a combination of both elevated triglycerides (≥200mg/dl), and elevated cholesterol levels. According to the National Cholesterol Education Program (NCEP), mixed dyslipidemia affects approximately 30 to 35 million Americans.

Multiple epidemiological, clinical, and genetic studies suggest that patients with severe hypertriglyceridemia (TGs≥500 mg/dL) are at a much greater risk for pancreatitis, a potentially life-threatening condition. Elevated TG levels are also strongly linked to a higher risk for heart disease and stroke, especially so with low levels of high-density lipoprotein cholesterol (HDL-C) and/or elevated levels of low-density lipoprotein cholesterol (LDL-C). Furthermore, the genes regulating both TGs and LDL-C are equally strong predictors of CAD, unlike HDL-C which is not. Thus, TGs and TG-rich lipoproteins have come to be recognized as an important factor contributing to Atherosclerotic Cardiovascular Disease (ASCVD).

There are currently approximately 92 million (more than 1 out of every 3) adults in the United States with one or more types of cardiovascular disease; an estimated 800,000 new or recurrent coronary events and 795,000 new or recurrent strokes occur each year. Heart attacks, strokes and other cardiovascular events represent the leading cause of death and disability among men and women in western societies.

Recent ASCVD Guidelines from The American Diabetes Association (ADA), the European Society of Cardiology/European Atherosclerosis Society (ESC/EAS), National Lipid Association (NLA) and American Association of Clinical Endocrinology/American College of Endocrinology (AACE/ACE) as well as a recent Scientific Advisory from the American Heart Association (AHA) have all advocated the use of an omega-3 product (icosapent ethyl) in patients at high CV risk who have persistently high TGs (> 135 mg/dL) despite statin therapy.

Current guidelines for the management of very high triglyceride levels (≥500 mg/dL) suggest that reducing triglyceride levels is the primary treatment goal in these patients to reduce the risk of acute pancreatitis, while treating LDL-C remains an important secondary goal. Other important parameters to consider in patients with very high triglycerides include levels of apolipoprotein B (apo B), non-HDL-C, and very low-density lipoprotein cholesterol (VLDL-C).

Current Treatment Options

The dramatic rise in obesity over the last few decades is strongly linked to concomitant increases in population cholesterol and triglyceride levels. Observational studies have highlighted the critical role that high cholesterol and high triglyceride levels (collectively, “dyslipidemia”) have as a predictor of cardiovascular events. Accordingly, the introduction of new drugs and novel mechanisms of action to lower the risk of cardiovascular events has become a priority. The initial treatment recommendation for patients with dyslipidemia is typically a low-fat diet. If diet alone is not effective, dyslipidemia is then often treated with statins, which account for approximately 80% of all dyslipidemia prescriptions. Statins as a class have been shown to not only lower blood cholesterol levels, but have also been shown in multiple studies to reduce the risk of heart attacks, strokes, and other adverse cardiovascular events. At present statins are utilized in almost 40% of patients with dyslipidemia in the United States. The primary effect of statins is to reduce LDL-cholesterol, with only modest effects on triglycerides. Recognizing that both cholesterol and triglycerides contribute to cardiovascular risk, and that statins alone are not always effective triglyceride lowering drugs, the National Cholesterol Education Program panel recommends the use of additional therapies to lower triglyceride levels in patients with SHTG. Fibrates, niacin, and omega-3-based medications have all been utilized to lower triglycerides levels.

The overall treatment rate of patients with HTG has remained relatively low. It is estimated that less than ten percent of the adult population with SHTG actually receives therapy beyond statins. Historically, fibrates such as gemfibrozil (Lopid) and fenofibrate (Tricor or Trilipix) were leading treatments for HTG. However, due to their inability to establish clinical outcome benefits and their limited compatibility with statin therapy, fibrate utilization has remained relatively low and is currently declining. Other niacin-containing products used to treat SHTG have not been able to establish additional outcome benefits beyond statin treatment alone, and their use is also declining. In patients with SHTG, many of whom are already receiving a statin, first-line drug therapy is often a prescription omega-3 product, which have been shown to reduce triglycerides in the range of 20%-45%.

The global prescription omega-3 market has been growing steadily over the last two decades; we estimate the market currently is approaching $2 billion in global sales. The leading omega-3 prescription pharmaceutical products currently approved for the treatment of HTG are Glaxo Smith Kline’s Lovaza (omega-3-acid ethyl esters, an omega-3 mixture containing mostly EPA and DHA, originally approved in the US in 2004, branded as Omacor in the rest of the world), Amarin’s Vascepa (an ethyl ester formulation of primarily EPA), approved in 2014 in the United States, Omacor and Seacor, (which are very similar to Lovaza and marketed in Europe); and Mochida Pharmaceutical’s Epadel (98% ethyl eicosapentaenoate), an ethyl ester formulation of EPA, the leading Japanese omega-3 product. In addition, Astra Zeneca’s omega-3, Epanova, a free fatty acid formulation of EPA and DHA was approved in the US in 2016 but has not been launched. Until recently, all prescription omega-3 products in the US were only approved for SHTG, but in December of 2019 Vascepa was approved in the US for the reduction of cardiovascular risk in high-risk patients with TGs > 150 mg/dL despite statin therapy. This approval was based upon data generated in a large, multi-year, multi-center outcomes study of Vascepa called REDUCE-IT.

The REDUCE-IT study was a multicenter, randomized, double-blind, placebo-controlled trial of Vascepa in patients at high cardiovascular risk with elevated triglycerides despite statin therapy. A total of 8,179 patients with established cardiovascular disease or with diabetes and other risk factors, who had been receiving statin therapy and who had fasting TGs of 135 to 499 mg/dL and LDL-C levels of 41 to 100 mg/dL were randomized to 2 g of Vascepa twice daily (total daily dose 4 g) or placebo (mineral oil). The primary endpoint was a composite of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or unstable angina. The key secondary end point was a composite of cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke. Median follow-up was 4.9 years.

In the 8,179 patients enrolled (71 % secondary prevention, 29% primary prevention) primary endpoints occurred in 17.2% of the Vascepa-treated patients and 22.0% of the placebo patients (HR 0.75; p<0.001); corresponding key secondary end point event rates were 11.2% and 14.8%, respectively (HR 0.74; p<0.001). There were also significant

reductions with Vascepa in the rates of fatal/non-fatal MI (HR 0.69; p<0.001), urgent/emergent coronary revascularization (HR 0.65; p<0.001), cardiovascular death (HR 0.80; p=0.03) hospitalization for unstable angina (HR 0.68; p=0.002) and fatal/non-fatal stroke (HR 0.72; p=0.01). From a safety standpoint, a slightly more patients in the Vascepa group were hospitalized for atrial fibrillation or flutter (3.1% vs. 2.1%, p=0.004), and serious bleeding events were slightly more frequent with Vascepa (2.7% vs 2.1%, p = 0.06).

One very important piece of information to emerge from REDUCE-IT was the importance of EPA blood levels. In REDUCE-IT, EPA levels were the only biomarker that was significantly correlated with clinical benefit, across a wide spectrum of cardiovascular outcomes. Changes in TGs, LDL-C, non-HDL, apoB and CRP were all not predictive of better outcomes with Vascepa in the REDUCE-IT trial. Importantly, there was a significant continuous relationship between EPA levels and outcome for the primary and key secondary endpoints. The higher the EPA level, the lower the hazard ration for adverse events, and the better the outcomes in REDUCE-IT.

LYPDISO Development History and Plan

We completed the first preclinical studies of LYPDISO in 2013 with others completed during 2014. In 2015, we announced results from an open-label head-to-head PK/PD Trial of LYPDISO against Vascepa in patients with elevated triglyceride levels. This crossover study demonstrated superior bioavailability of LYPDISO, along with greater efficacy in reducing serum triglycerides, total- and non-HDL-cholesterol, apolipoprotein CIII and PCSK9 levels. Forty-two patients were treated with 4 grams/day of LYPDISO or Vascepa for 14 days, followed by a 5-week wash-out period and crossed over to the other treatment for another 14 days of treatment. Study subjects were required to have fasting TG levels of 200-400 mg/dl without lipid altering therapy, or fasting TG levels of 200 to 350 mg/dL if they were on stable-dose statin monotherapy. Forty patients completed both arms of the trial. In comparison to Vascepa, treatment with LYPDISO provided significantly greater reductions in TGs, very low-density lipoprotein cholesterol (VLDL) non-HDL cholesterol, total cholesterol, apolipoprotein AI, apolipoprotein CIII, and PCSK9. In additional, LYPDISO achieved significantly higher blood levels of EPA.

Following initial announcement of these data in 2015, due primarily to cardiovascular regulatory and commercial market conditions, as well as limited financial resources, we postponed further development of LYPDISO until such time as data could became available from REDUCE-IT. The REDUCE-IT data were announced in the fall of 2018, and as previously noted, there was robust clinical benefit in 8,000+ higher-risk patients with elevated triglycerides despite adequate LDL-C control with statins, with no statistical heterogeneity between the primary and secondary prevention cohorts. Following the release of these data, we promptly re-activated our development program for LYPDISO.

The development program for LYPDISO was initially designed to (a) complete studies required for approval for an initial indication to treat SHTG and, (b) complete additional trials to demonstrate the differentiation of LYPDISO vs. other approved omega-3 products while creating the potential for subsequent label enhancement in a broader dyslipidemic patient population. The IND was reactivated in the second quarter of 2019.

During the second half of 2019 and the first quarter of 2020 we completed a 28-day preclinical comparative bridging toxicology study, initiated and competed the in-life portion of an additional 90-day preclinical comparative bridging toxicology study, and initiated and completed the clinical dosing for a comparative 4-way crossover clinical bioavailability study versus Lovaza in 36 healthy volunteers. Lovaza was identified as the reference-listed drug under Section 505(b)(2) to FDA as part of the regulatory strategy for approval of LYPDISO. The comparative bioavailability study to Lovaza involved an open label, single-dose, randomized, 4-way crossover comparison of 4g of LYPDISO to 4g of Lovaza, under both fasted and fed conditions (high-calorie, high-fat breakfast). Treatments were administered with at least 14 days between each dosing. Plasma free and total EPA, DPA and DHA were measured at baseline and at specified timepoints up to 48-hours post-dose to assess bioavailability. Key areas of interest were baseline-free adjusted free and total EPA (primary) and baseline-adjusted free and total DPA (secondary). Under fasted conditions, baseline-adjusted total EPA and total DPA were substantially higher for LYPDISO compared with Lovaza. Similar findings were noted for free EPA and free DPA. Under fed conditions, the absorption of Lovaza improved substantially, while that of LYPDISO improved slightly. Total omega-3 levels (EPA + DPA + DHA) were approximately 50-60% higher with LYPDISO than with Lovaza after a high fat meal. Given that in the fasted state LYPDISO was very well absorbed, with only a minimal food effect, whereas Lovaza was poorly absorbed unless taken with a high fate meal, this indicated that the free fatty acid formulation of LYPDISO provided improved absorption with a minimal food effect and without the need for a high fat meal for effective absorption. Key endpoints and assessments include PK parameters (e.g., AUC, C_{max}, T_{max}, $t_{1/2}$) for total EPA, DHA and DPA and comparison of PK parameters for LYPDISO in the fasted and fed (high fat meal) state.

In August of 2020 we held an End-of-Phase 2 Meeting with FDA to review the results of the preclinical and comparative bioavailability studies, and to discuss issues related to an approval in SHTG. The FDA provided feedback that: 1) with these preclinical and comparative bioavailability data in-hand, a 505(b)(2) registration pathway was reasonable; 2) a single placebo-controlled Phase 3 trial would likely be sufficient to establish efficacy in SHTG, and 3) the necessary safety database for approval could be supplement with other patients, including patients with SHTG.

In parallel with the preclinical and clinical studies necessary for FDA approval, we have also recently completed the ENHANCE-IT study, an additional clinical study intended to differentiate LYPDISO from Vascepa, widely considered the leading prescription omega-3 drug. ENHANCE-IT was a randomized, open-label, parallel-group, crossover study designed to assess and compare the effects of LYPDISO and Vascepa on lipid markers and blood omega-3 levels. It included 100 adult men and women with elevated triglycerides (150-499 mg/dL); approximately 58% of study subjects had TGs ≥ 200 mg/dL. The study protocol involved two 28-day treatment periods, with a washout period of at least 28 days between treatments and was conducted at 8 sites in the U.S. LYPDISO and Vascepa were each given as 2g twice daily with food in accordance with the approved Vascepa labeling. Baseline and post-treatment measurements included triglycerides, Total-, LDL-, VLDL-, HDL- and non-HDL cholesterol, apolipoproteins A1, B and C3 and PCSK9, as well as hs-CRP. An additional important endpoint was omega-3 blood levels, including EPA, DPA, DHA and total levels for both treatment periods. The primary endpoint in ENHANCE-IT was the percent change from baseline to end-of-treatment in plasma triglycerides. The first subject as randomized in June of 2020, enrollment was completed by the end of August, last-patient, last-visit was at the end of November and the database was locked in mid-January 2021.

In February 2021 we announced topline data from the ENHANCE-IT trial. Two analysis populations were prespecified in the statistical analysis plan: a pharmacodynamic (PD) population (94 patients), and a per-protocol (PP) population (82 patients). The PD population included all subjects for whom estimation of pharmacodynamic parameters was possible for both treatment periods, regardless of study drug compliance. The PP population included patients from the PD population, with the added stipulation of at least 80% compliance with study medications (verified by pill counts), with no clinically important protocol violations or deviations. The PP population group was expected to have less variability due to poor study drug compliance, and to provide a more accurate representation of how each study drug (LYPDISO or Vascepa) would perform when taken as directed.

The topline results from ENHANCE-IT were as follows:

- The primary endpoint (% change in TG from baseline) was numerically greater with LYPDISO vs. Vascepa (21.9% vs. 15.7%) but did not meet statistical significance in the prespecified PD population. Statistical significance as achieved in the PP population (20.9% vs. 13.8%).
- Plasma EPA concentrations, absolute change from baseline and % change from baseline were all significantly higher with LYPDISO than with Vascepa, in both the PD and PP populations (46% relative percent increase change from baseline EPA with LYPDISO vs. Vascepa).
- There were also significant reductions in hs-CRP with LYPDISO as compared with Vascepa, suggesting the potential superior anti-inflammatory impact of LYPDISO.
- There were no serious adverse events reported and no dropouts related to study drug adverse events.

Variable*	PD Population (N = 94) Median % Δ		P-value
	LYPDISO™	Vascepa®	
TG	- 21.9	- 15.7	0.27
TC	- 5.2	- 2.9	0.17
LDL-C	- 5.4	- 2.5	0.24
VLDL-C	- 16.3	- 12.9	0.26
HDL-C	- 1.3	- 1.5	0.69
Non-HDL-C	- 7.5	- 3.8	0.19
Apo A1	- 5.0	- 3.5	0.46
Apo B	- 4.7	- 1.9	0.54
Apo C3	- 12.5	- 10.5	0.53
PCSK9	- 7.7	- 6.1	0.80
hs-CRP	**- 5.7**	**+ 9.4**	**0.03**

*Units of mg/dL for lipoprotein lipids, units of ng/mL for PCSK9, and units of mg/L for hs-CRP

Variable**	PP Population (N = 82) Median % Δ		P-value
	LYPDISO™	Vascepa®	
TG	**- 20.9***	**-13.8**	**0.04**
TC	**- 5.5***	**- 2.3**	**0.04**
LDL-C	- 5.6	- 2.1	0.17
VLDL-C	**- 16.0***	**- 10.9**	**0.03**
HDL-C	- 1.6	- 2.0	0.52
Non-HDL-C	- 7.6	- 3.2	0.07
Apo A1	- 5.0	- 2.9	0.44
Apo B	- 4.1	- 1.8	0.60
Apo C3	- 11.1	- 8.7	0.10
PCSK9	- 6.7	- 5.5	0.68
hs-CRP	**- 6.1***	**+ 9.9**	**0.01**

**Units of mg/dL for lipoprotein lipids, units of ng/mL for PCSK9, and units of mg/L for hs-CRP

PD Population (n=94)								
Fatty Acid	Baseline (Median)		End-of-Treatment (Median)		% Δ from Baseline (Median)		*Relative % Increase in Omega-3 level Δ vs. Vascepa*	*P-value*
	LYPDISO™	Vascepa®	LYPDISO™	Vascepa®	LYPDISO™	Vascepa®		
EPA (µg/mL)	**13.8**	**15.5**	**143**	**115**	**1009**	**690**	**46 %**	**<0.001**
DPA (µg/mL)	**20.3**	**20.7**	**57.8**	**50.3**	**183**	**145**	**26 %**	**<0.001**
DHA (µg/mL)	**48.6**	**50.2**	**49.7**	**48.1**	**4.5**	**-1.4**	**--**	**0.01**
EPA+DPA+DHA (nmol/mL)	**254**	**263**	**789**	**696**	**221**	**160**	**38 %**	**<0.001**

These results provided important information about the potential role of LYPDISO in the management of patients with elevated triglycerides and cardiovascular disease and highlighted the differentiation from Vascepa and generic copies of Vascepa in the omega-3 class. The results of ENHANCE-IT suggest meaningful opportunities for LYPDISO as a best-in-class prescription omega-3 product for cardiovascular risk reduction. Given the significant time and cost associated with cardiovascular outcomes clinical trials, we have initiated a process to identify a partner to advance development of LYPDISO. We have allocated resources away from a Phase 3 program in SHTG and will focus our internal resources primarily on advancement of our LNC platform delivery technology.

Strategic Collaborations Using LNC Platform Delivery Technology

We believe our LNC platform delivery technology can be used to reformulate a wide variety of molecules and drugs which, (i) require delivery technology to effectively protect molecules and drugs in the body and could benefit from efficient delivery and cellular uptake by target cells, and (ii) are currently only available in IV formulations or, (iii) otherwise experience significant toxicity-related adverse events. We have tested a range of pharmaceutical compounds reformulated by our LNC platform delivery technology in proof-of-concept animal studies, including oligonucleotides (mRNA, siRNA, DNA plasmids), vaccines, anti-inflammatory agents, NSAIDs and atovaquone. We intend to pursue opportunities to develop products, either alone or in partnership with other pharmaceutical or biotech companies, related to this technology and this remains a key part of our strategy to maximize the value of this unique and disruptive lipid-crystal nanoparticle delivery technology.

In January 2019 we announced a research evaluation with an undisclosed top global pharmaceutical company aimed to evaluate synergistic effects of our LNC platform delivery technology with our partner's nucleic acid polymer technology. Formulations will be developed using our LNC platform delivery technology which enables the development of a wide range of difficult-to-deliver molecules. Promising formulations will be tested in *in vitro* and *in vivo* preclinical studies. For competitive reasons, the agreement stipulates certain confidential provisions, including the pharmaceutical company's identity, the therapeutic molecule(s), the intended targets and the financial terms of the agreement.

In May 2019 we announced a research collaboration with ViiV Healthcare, a global specialist HIV company established by GlaxoSmithKline and Pfizer dedicated to delivering advances in the treatment and care of people living with HIV or who are at risk for developing HIV. As part of this collaboration, formulations of select antivirals will be developed using our LNC platform delivery technology. Promising formulations will be tested in in vivo preclinical studies to identify a lead LNC antiviral formulation to take forward in development. Due to the global pandemic, progress on this program has been limited due to competing ViiV Healthcare priorities.

In December 2019, we announced a feasibility collaboration with Genentech, a Roche company, to evaluate formulations of a number of Genentech compounds utilizing our LNC platform delivery technology. During 2020 we made progress in formulating two molecules from this collaboration and continue to work with Genentech to evaluate these formulations and plan for additional preclinical studies.

In December 2020, we announced a collaboration with the National Institute of Allergy and Infectious Diseases (NIAID) to develop oral formulations of Gilead's remdesivir, which is currently only available as an intravenous therapy in the fight against COVID-19. We believe the attributes of our LNC platform technology will allow for oral bioavailability and efficient intracellular delivery. We have begun formulating remdesivir and preparing to deliver formulations to NIAID for *in vitro* preclinical studies in COVID-19 models. If successful, the formulations will proceed to *in vivo* testing later in 2021.

We continue to evaluate additional potential strategic collaborations with other interested biotech and pharmaceutical partners. These early stage, proof-of-concept evaluations could provide an efficient, less expensive pathway to create numerous strategic verticals in areas of innovative medicine while capitalizing on the development expertise and financial resources of well-established pharmaceutical and biotech companies. Data from these evaluations could position us as a licensor of our LNC platform delivery technology to numerous strategic partners better positioned to absorb the risks and costs of drug development while allowing our company to become a royalty aggregator with the potential to generate upfront license, milestone and royalty payments as we maximize the value of the overall LNC platform delivery technology.

Exclusive License Agreement with Rutgers University

Through our acquisition of Aquarius Biotechnologies Inc., we acquired a license from Rutgers University for the LNC platform delivery technology. The Amended and Restated Exclusive License Agreement between Aquarius and Rutgers, The State University of New Jersey (successor in interest to the University of Medicine and Dentistry of New Jersey) provides for, among other things, (1) a license issue fee of $25,000 paid upon execution, (2) an increased equity interest in the company from 5% to 7.5% of Aquarius (prior to our acquisition of Aquarius in the Aquarius Merger), (3) royalties on a tiered basis between low single digits and the mid-single digits of net sales of products using such licensed technology, (4) a one-time sales milestone fee of $100,000 when and if sales of products using the licensed technology reach the specified sales threshold and (5) an annual license fee of initially $10,000, increasing to $50,000 over the term of the license agreement. We also agreed to assume the responsibility to pay required patent prosecution and maintenance fees covering the technology.

Unless otherwise terminated by either party, the term of the license, on a country-by-country basis, shall be the longer of 7-1/2 years from the date of first commercial sale of a product in a country using the licensed technology or until the expiration of the last-to-expire patent rights licensed under the agreement, whichever is longer. Rutgers has the right to terminate the license agreement if we have not commenced commercial sales of at least one product using the licensed technology within nine years of the effective date of the license agreement.

Intellectual Property

The proprietary nature of, and protection for, our product candidates and our discovery programs, processes and know-how are important to our business. We will seek to protect our products and associated technologies for their manufacturing and development through a combination of patents, trade secrets, proprietary know-how, FDA exclusivity and contractual restrictions on disclosure. Our policy is to pursue, maintain and defend patent rights and to protect the technology, inventions and improvements that are commercially important to the development of our business. Our success will significantly depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology and inventions and know-how related to our business, defend and enforce our patents, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely heavily on know-how and continuing technological innovation to develop and maintain our proprietary position.

Matinas-Owned Intellectual Property Relating to LYPDISO

We have sought patent protection in the United States and internationally for our LYPDISO discovery program, and any other inventions to which we have rights, where available and when appropriate. Our policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business.

Our current patent portfolio relating to LYPDISO is comprised of two issued U.S. patents and one issued foreign patent in Australia. The issued patents cover the Company's proprietary methods relating to triglyceride levels, total cholesterol, VLDL-cholesterol or apolipoprotein C-III by administering a pharmaceutical composition comprising omega-3 fatty acids including eicosapentaenoic acid (EPA) and docosapentaenoic acid (DPA). These patents provide important protection to LYPDISO through 2033. In addition, we have eight additional patent applications across four patent families covering the oil composition for LYPDISO, other omega-3 fatty acid compositions, as well as formulations of LYPDISO and similar formulations. All of these filed patent applications also comprise methods of use of such oil compositions and formulations. Any patents that may issue from these filed United States patent applications and their counterpart international application covering the LYPDISO drug substance, formulation, and methods for use in treatment would extend protection until at least 2033.

Exclusively Licensed and Matinas-Owned Intellectual Property Relating to Our Proprietary LNC Platform Delivery Technology and MAT2203

The patents and patent applications that we exclusively license from Rutgers University provide patent protection for the proprietary chemistry technology used in our process to make our lipid nanocrystal and geodate cochleates and formulate the active pharmaceutical ingredients delivered inside this delivery technology, as in MAT2203, our lead product comprising the LNC platform delivery technology. Pursuant to our license agreement, we acquired rights to a portfolio that currently includes 2 pending applications and 30 issued U.S. and foreign patents, including 24 patents issued within the last 5 years, which extends patent protection until at least 2033. In addition, we have over 20 Matinas-owned pending patent applications filed both in the United States and in foreign jurisdictions within the past 5 years. We have chosen to file these patent applications in selected foreign markets that we consider important for our product candidates. These international markets generally include Europe, China, India, Brazil, Russia, Canada, Japan, Korea, Australia and Mexico. These pending patent applications can extend patent protection through 2040. This patent portfolio covers our LNC platform delivery technology which covers a broad spectrum of technology, including amphotericin B LNCs, geodate LNCs, methods of delivering nutrients or biologically relevant molecules to a host using LNCs, LNC vaccine compositions and protein-lipid vesicles, small interfering RNA LNCs, methods of enhancing the LNC encapsulation of hydrophilic molecules, LNCs made with low purity soy phosphatidylserine, methods of treating Mycobacterial infections, and methods of treating cryptococcus infections.

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. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors—Risks Relating to Our Intellectual Property and Regulatory Exclusivity."

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, significant aspects of our proprietary LNC platform delivery technology as well as the manufacture of certain intermediates utilized in LYPDISO, as well as our soft gelatin capsule formulation, are based on unpatented trade secrets and know-how. Trade secrets and know-how can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We also plan to seek trademark protection in the United States and outside of the United States where available and when appropriate. We intend to use these registered marks in connection with our pharmaceutical research and development as well as our product candidates.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Many of these companies have far greater human and financial resources and may have product candidates in more advanced stages of development and many will reach the market before our product candidates. Competitors may also develop products that are more effective, safer or less expensive or that have better tolerability or convenience.

LYPDISO

Our competitors, both in the United States and abroad, include large, well-established pharmaceutical and generic companies, specialty and generic pharmaceutical sales and marketing companies, and specialized cardiovascular treatment companies. GlaxoSmithKline plc currently sells Lovaza®, a prescription-only omega-3 fatty acid indicated for patients with SHTG, which was approved by FDA in 2004 and has been on the market in the United States since 2005. Multiple generic versions of Lovaza are available in the

United States. Other large companies with competitive products include AbbVie, Inc., which currently sells Tricor® and Trilipix® for the treatment of SHTG and Niaspan®, which is primarily used to raise high-density lipoprotein cholesterol, or HDL-C, but is also used to lower triglycerides. Multiple generic versions of Tricor, Trilipix and Niaspan are also available in the United States. In 2012, Amarin Corporation received an approval to market its prescription-only omega-3 ethyl ester called Vascepa® for the treatment of SHTG. In December of 2019 Vascepa was approved in the US for the reduction of cardiovascular risk in high-risk patients with TGs > 150 mg/dL despite statin therapy. In January of 2021, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended approval for Vazkepa (Vascepa) in the EU for a similar indication. Approval of Vazkepa is expected in the second quarter of 2021.

In addition, in May 2014, Epanova® (omega-3-carboxylic acids) capsules, a free fatty acid form of omega-3 (comprised of 55% EPA and 20% DHA), was approved by the FDA for patients with SHTG. Epanova was developed by Omthera Pharmaceuticals, Inc., and is now owned by AstraZeneca Pharmaceuticals LP (AstraZeneca). To date, AstraZeneca has not launched Epanova in the United States or in any other territory around the world but did conduct the STRENGTH study (a long-term outcomes study to assess **ST**atin **R**esidual risk reduction with **E**pa**N**ova in hi**G**h cardiovascular risk patien**T**s with **H**ypertriglyceridemia). STRENGTH was a randomized, double-blind, placebo-controlled (corn oil), parallel group design study that enrolled approximately 13,000 patients with HTG and low HDL and high risk for cardiovascular disease, randomized 1:1 to either corn oil plus statin or Epanova plus statin, once daily. In January 2020, following the recommendation of an independent data monitoring committee, AstraZeneca decided to end the STRENGTH trial due to a low likelihood of Epanova having any demonstrable benefit in the study. Final results were published in November of 2020.

In addition, in March 2017, Kowa Research Institute (a subsidiary of the Japanese company Kowa Co., Ltd.) initiated a Phase 3 cardiovascular outcomes trial titled PROMINENT, examining the effect of pemafibrate in reducing cardiovascular events in Type II diabetic patients with HTG. Kowa Research Institute has publicly estimated study completion in May 2022, and if successful, US regulatory approval is estimate mid-2023.

During 2018, two outcomes studies were completed of omega-3 mixtures which both failed to achieve their primary endpoints of cardiovascular risk reduction and two meta-analyses were published showing that omega-3 mixtures are not effective in lowering cardiovascular risk. Results of these failed outcomes studies and analysis, while not done with LYPDISO, may negatively affect utilization of LYPDISO, if approved. For example, the VITamin D and OmegA-3 TriaL (VITAL), failed to achieve its primary endpoint of lowering cardiovascular events. VITAL was an NIH funded randomized double-blind, placebo-controlled, 2x2 factorial trial of 2000 IU per day of vitamin D3 and 1 gram per day of omega-3 fatty acid mixture supplementation (Lovaza) for the primary prevention of cancer and cardiovascular disease in a nationwide US cohort of 25,874 adults not selected for elevated cardiovascular or cancer risk. Likewise, in 2018, results from A Study of Cardiovascular Events iN Diabetes (ASCEND) trial were released and showed negligible results for omega-3 fatty acid mixtures 1 gram daily. ASCEND was a British Heart Foundation funded 2x2 factorial design, randomized study to assess whether aspirin 100 mg daily versus placebo and separately, omega-3 fatty acid mixtures 1 gram daily versus placebo, reduce the risk of cardiovascular events in a nationwide UK cohort of over 15,000 individuals with diabetes who do not have atherosclerotic cardiovascular disease. In a meta-analysis, presented in 2018 by the Cochran Foundation and separately as published in JAMA, additional omega-3 studies were evaluated. Similar to the VITAL and ASCEND studies, most of the studies in these omega-3 meta-analyses were of omega-3 mixtures, including DHA, and most were studies of relatively low doses of omega-3 as is associated with dietary supplementation and/or they studied relatively low risk patient populations. The exception was the JELIS study, conducted in Japan, of highly pure EPA which showed a positive outcome benefit but had significant limitations in its application to a wider population. The negative results from such omega-3 mixture studies could create misleading impressions about the use of omega-3s generally, including LYPDISO, despite the unique combination of active ingredients in LYPDISO and its higher dose regimen.

MAT2203 and MAT2501

Although we believe that our proprietary LNC platform delivery technology, experience and knowledge in our areas of focus provide us with competitive advantages, these potential competitors could reduce our commercial opportunities. For many of our product candidates, we anticipate facing competition from other products that are available on a generic basis and offered at low prices. Many of these generic products have been marketed by third parties for many years and are well accepted by physicians, patients and payers.

We believe that MAT2203 and MAT2501 and any other development candidate we may pursue in the future using our proprietary LNC platform delivery technology, paralleled with our scientific and development expertise in the field of drug delivery, provide us with competitive advantages over our peers. However, we face potential competition from various sources, including larger and better-funded pharmaceutical, specialty pharmaceutical, and biotechnology companies, as well as from generic drug manufacturers, academic institutions, governmental agencies and public and private research institutions.

MAT2203 will primarily compete with antifungal classes approved for the treatment of fungal and mold infections, which include polyenes, azoles and echinocandins. The approved branded therapies for these indications include Cancidas (caspofungin, marketed by Merck & Co.), Eraxis (anidulafungin, marketed by Pfizer, Inc.), Mycamine (micafungin, marketed by Astellas Pharma US, Inc.), Diflucan (fluconazole, marketed by Pfizer, Inc.), Noxafil (posaconazole, marketed by Merck & Co.), Vfend (voriconazole, marketed by Pfizer, Inc.), Sporanox (itraconazole, marketed by Jansen Pharmaceuticals, Inc.), Cresemba (isavuconazole, marketed by Astellas Pharma US, Inc.), Ambisome (liposomal amphotericin B, marketed by Astellas Pharma US, Inc.) Abelcet (lipid complex amphotericin B, marketed by Sigma Tau Pharmaceuticals Inc.) and amphotericin B deoxycholate (marketed by X-Gen Pharmaceuticals, Inc.). There currently are and may be more generic versions of these products available at the time of MAT2203 market approval, which will create added competition. In addition to approved therapies, we expect that MAT2203 may compete with product candidates that we are aware of in clinical development by third parties, such as SCY-078 (being developed by Scynexis, Inc.), rezafungin acetate (being developed by Cidara Therapeutics, Inc.) and certain products being developed by Viamet Pharmaceuticals Holdings, LLC, Vical Incorporated and F2G, Ltd.

MAT2501 will primarily compete with aminoglycosides indicated for the treatment of NTM lung infections and will include Arikayce®, an inhaled formulation of amikacin (marketed by Insmed) and IV amikacin (Amikin; marketed by Bristol Myers Squibb) as well as a number of generic manufacturers of IV amikacin.

Manufacturing

We currently engage with multiple third-party manufacturers to supply us with certain of the intermediates used in LYPDISO and an additional manufacturer to formulate a third intermediate and supply us with the final drug form. We have an additional manufacturer which fills and provides our final LYPDISO capsules. If any of these manufacturers should become unavailable to us for any reason, we have identified a number of potential replacements, although we might incur some delay in qualifying such replacements. We expect to add additional suppliers and manufacturers for both the intermediates and final LYPDISO drug product as we advance LYPDISO further into clinical development.

We currently lease and operate in-house manufacturing capabilities for our lead LNC platform delivery technology product candidate, MAT2203, MAT2501, and for our LNC platform discovery programs in the gene therapy and vaccine spaces. While sufficient to produce the clinical supplies of product necessary to conduct our ongoing clinical trials and potentially early commercialization of MAT2203 and MAT2501, we may need to expand our internal manufacturing capabilities in the future. If we are not able to retain our current manufacturing facilities and if we do not develop additional in-house manufacturing capability for our MAT2203, MAT2501 and product candidates sufficient to produce product for commercialization of these products, we will need to develop relationships with third-party manufacturers for the manufacture of our product candidates which could be time consuming and expensive. We are in the process of identifying a third-party contract manufacturer for MAT2203 and other products derived from our LNC platform technology.

There are a number of potential third-party suppliers for amphotericin B, the generic active pharmaceutical ingredient in our lead clinical stage product candidate – MAT2203 and for amikacin, the generic active pharmaceutical ingredient in our preclinical LNC product candidate – MAT2501. Although to date we have not entered into formal supply

agreements to secure sufficient supply of amphotericin B or amikacin to support our clinical programs for MAT2203 or MAT2501, we believe we will be able to secure supply of amphotericin B and amikacin to support our clinical programs for MAT2203 and MAT2501 and from one or more third-party suppliers. As we move through development for our product candidates, we expect to enter into long term supply arrangements for key active pharmaceutical ingredients.

Sales and Marketing

We currently do not have any sales and marketing infrastructure. We plan to retain U.S. marketing and sales rights or co-promotion rights for our product candidates for which we receive marketing approvals, particularly in situations where it is possible to access the market through a focused, specialized sales force. For situations in which a large sales force is required to access the market, and with respect to markets outside the United States, we generally plan to commercialize our product candidates through collaborative arrangements with leading pharmaceutical and biotechnology companies.

Review and Approval of Drugs in the United States

In the United States, FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by FDA to approve pending applications, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters and other types of letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by FDA and the Department of Justice, or DOJ, or other governmental entities.

Our product candidates must be approved by FDA through the new drug application, or NDA, or biologics license application, or BLA, in the case of biologic product candidates, process before they may be legally marketed in the United States. An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- completion of nonclinical laboratory tests, animal studies and formulation studies in compliance with FDA's good laboratory practice, or cGLP, regulations;
- submission to FDA of an IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to FDA of an NDA or BLA;
- review of the product by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with current Good Manufacturing Practices, or cGMP, requirements and to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- payment of user fees and securing FDA approval of the NDA or BLA; and
- compliance with any post-approval requirements, including a risk evaluation and mitigation strategy, or REMS, and post-approval studies required by FDA.

Nonclinical Studies

Nonclinical studies include laboratory evaluation of the purity and stability of the manufactured drug substance or active pharmaceutical ingredient and the formulated drug or drug product, as well as *in vitro* and animal studies to assess the safety and activity of the drug for initial testing in humans and to establish a rationale for therapeutic use. The conduct of nonclinical studies is subject to federal regulations and requirements, including cGLP regulations. The results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to FDA as part of an investigational new drug application, or IND.

Companies usually must complete some long-term nonclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Human Clinical Trials in Support of a Regulatory Approval

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to FDA as part of the IND. An IND automatically becomes effective 30 days after receipt by FDA, unless before that time FDA raises concerns or questions related to a proposed clinical trial and places the trial on clinical hold. In such a case, the IND sponsor and FDA must resolve any outstanding concerns before the clinical trial can begin. Accordingly, submission of an IND may or may not result in FDA allowing clinical trials to commence.

In addition, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their ClinicalTrials.gov website.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. When a foreign clinical study is conducted under an IND, all FDA IND requirements must be met unless waived. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to FDA in support of an NDA or IND so long as the clinical trial is conducted in accordance with GCP and if FDA is able to validate the

data from the clinical trial through an on-site inspection, if FDA deems it necessary.

Human clinical trials are typically conducted in three sequential phases, which may overlap or be combined:

Phase 1: The drug is initially introduced into a small number of healthy human subjects or patients with the target disease (e.g. cancer) or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.

Phase 2: The drug is administered to a larger number of trial participants, up to several hundred, who usually have the disease or condition that the experimental drug is intended to treat, to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3: These clinical trials are commonly referred to as "pivotal" studies, which typically denotes a study which presents the data that FDA or other relevant regulatory agency will use to determine whether or not to approve a drug. In Phase 3 clinical trials, the drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product.

Progress reports detailing the results of the clinical trials must be submitted at least annually to FDA and more frequently if serious adverse events occur. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. Furthermore, FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Submission of an NDA to FDA

Regulatory approval for most new drug or biologic products is based on two adequate and well-controlled Phase 3 clinical trials that provide evidence of the safety and efficacy of the proposed new product. Assuming successful completion of required clinical testing and other requirements, the results of the nonclinical and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to FDA as part of an NDA requesting approval to market the drug product for one or more indications. Under federal law, the submission of most NDAs is additionally subject to an application user fee and the sponsor of an approved NDA is also subject to annual prescription drug program fees and establishment user fees. These fees are typically increased annually.

FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after FDA's receipt of the submission whether the application is sufficiently complete to permit substantive review. FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before FDA accepts it for filing. Once the submission is accepted for filing, FDA begins an in-depth substantive review. FDA has agreed to specified performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. The review process may be extended by FDA for various reasons, and for various time periods, including for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by FDA following the original submission.

Before approving an NDA, FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections cover all facilities associated with an NDA submission, including drug component manufacturing (such as Active Pharmaceutical Ingredients), finished drug product manufacturing and control testing laboratories. FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, FDA will typically inspect one or more clinical sites to assure compliance with GCP.

FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Fast Track, Breakthrough Therapy and Priority Review Designations

FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs are fast track designation, breakthrough therapy designation and priority review designation.

Specifically, FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with FDA and FDA may initiate review of sections of a fast track product's NDA before the application is complete. This rolling review may be available if FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the NDA is submitted. In addition, the Fast Track designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Improvement Act, or FDASIA. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. FDA determines, on a case-by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting drug reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten FDA's goal for taking action on a marketing application from ten months to six months.

Under Section 524 of the FDCA, FDA is authorized to award a priority review voucher to sponsors of certain tropical disease product applications that meet the criteria specified in the Act. A priority review voucher may be used by the sponsor who obtains it, or it may be transferred to another sponsor who may use it to obtain priority review for a different application. Priority review vouchers can result in the acceleration of review and approval of a product candidate by up to four months. In order to be eligible for a tropical disease priority review voucher, the application must be: for a listed tropical disease; submitted under Section 505(b)(1) of the FDCA or Section 351 of the Public Health Service Act; for a product that contains no active ingredient that has been approved in any other application under those statutory provisions; and must qualify for priority review. FDA has identified in guidance those product applications for the prevention or treatment of tropical diseases that may qualify for a priority review voucher.

Accelerated Approval Pathway

FDA may grant accelerated approval to a drug for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and 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. Drugs granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. FDA has limited experience with accelerated approvals based on intermediate clinical endpoints but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a drug.

The accelerated approval pathway is most often used in settings in which the course of a disease is long, and an extended period of time is required to measure the intended clinical benefit of a drug, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow FDA to withdraw the drug from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by FDA.

FDA's Decision on an NDA

On the basis of FDA's evaluation of the NDA and accompanying information, including the results of the inspection of the manufacturing facilities, FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for FDA to reconsider the application. If and when those deficiencies have been addressed to FDA's satisfaction in a resubmission of the NDA, FDA will issue an approval letter. FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

If FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions which can materially affect the potential market and profitability of the product. In addition, as a condition of approval, FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events and whether the product is a new molecular entity. REMS can include medication guides, physician communication plans for healthcare professionals and elements to assure safe use, which may include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. FDA may require a REMS before approval or post-approval if it becomes aware of a serious risk associated with use of the product. The requirement for a REMS can materially affect the potential market and profitability of a product.

FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with FDA and state agencies and are subject to periodic unannounced inspections by FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning or untitled letters or holds on post-approval clinical trials;

- refusal of FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act, or PDMA, which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress authorized FDA to approve generic drugs that are the same as drugs previously approved by FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the nonclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug, or RLD.

Specifically, in order for an abbreviated new drug application, or ANDA to be approved, FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form and the strength of the drug. At the same time, FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug.

Upon approval of an ANDA, FDA indicates whether the generic product is therapeutically equivalent to the RLD in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations," also referred to as the "Orange Book." Physicians and pharmacists consider a therapeutically equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, FDA's designation of therapeutic equivalence often results in automatic substitution of the generic drug by the pharmacist without the knowledge or consent of either the prescribing physician or patient.

Under the Hatch-Waxman Amendments, FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be submitted to FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

Hatch-Waxman Patent Certification and the 30 Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with FDA each patent with claims that cover the applicant's product or an approved method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant submits its application to FDA, the applicant is required to certify to FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval. Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicate that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

Pediatric Studies and Exclusivity

Under the Pediatric Research Equity Act of 2003, an NDA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the drug product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. With enactment of the Food and Drug Administration Safety and Innovation Act, or FDASIA, in 2012, sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The applicant, FDA and FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. FDA or the applicant may request an amendment to the plan at any time.

FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in FDASIA.

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent exclusivity. This six-month exclusivity may be granted if an NDA sponsor

submits pediatric data that fairly respond to a written request from FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which FDA cannot approve another application.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product). A company must request orphan product designation before submitting a NDA. If the request is granted, FDA will disclose the identity of the therapeutic agent and its potential use. Orphan product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation, the product will be entitled to orphan product exclusivity. Orphan product exclusivity means that FDA may not approve any other applications for the same product for the same indication for seven years, except in certain limited circumstances. Competitors may receive approval of different products for the indication for which the orphan product has exclusivity and may obtain approval for the same product but for a different indication. If a drug or drug product designated as an orphan product ultimately receives marketing approval for an indication broader than what was designated in its orphan product application, it may not be entitled to exclusivity.

21st Century Cures Act

On December 13, 2016, Congress passed the 21st Century Cures Act, or the Cures Act. The Cures Act is designed to modernize and personalize healthcare, spur innovation and research, and streamline the discovery and development of new therapies through increased federal funding of particular programs. It authorizes increased funding for FDA to spend on innovation projects. The new law also amends the Public Health Service Act to reauthorize and expand funding for the National Institutes of Health. The Act establishes the NIH Innovation Fund to pay for the cost of development and implementation of a strategic plan, early-stage investigators and research. It also charges NIH with leading and coordinating expanded pediatric research. In addition, the Cures Act includes provisions requiring FDA to assess and publish guidance on the use of novel clinical trial designs, the use of real-world evidence in applications, the availability of summary level review for supplemental applications for certain indications, and the qualification of drug development tools. Because the Cures Act has only recently been enacted, its potential effect on our business remains unclear with the exception of a provision requiring that we post our policies on the availability of expanded access programs for individuals. Because these provisions allow FDA to spend several years developing these policies, the effect on us could be delayed.

With amendments to the FDCA and the Public Health Service Act, or PHSA, Title III of the Cures Act seeks to accelerate the discovery, development, and delivery of new medicines and medical technologies. To that end, and among other provisions, the Cures Act reauthorizes the existing priority review voucher program for certain drugs intended to treat rare pediatric diseases until 2020; creates a new priority review voucher program for drug applications determined to be material national security threat medical countermeasure applications; and revises the FDCA to streamline review of combination product applications.

Section 3042 of the Cures Act authorizes a new "Limited Population Pathway" to expedite approval of antimicrobial products intended to treat serious or life-threatening infections for which there are unmet medical needs. Drugs approved under this provision would be required to adhere to special labeling requirements, including a prominent "Limited Population" statement. Additionally, in recognition of increasing concerns about drug-resistant infections, the Act requires the U.S. Government Accountability Office (GAO) to compile a report on antimicrobial resistance by 2021, which would include a review of any effect of the new Limited Population Pathway on antibacterial or antifungal resistance. We will monitor these developments but cannot currently assess how this initiative may impact our business.

Other Health Care Regulations

Health Privacy Laws

We are subject to data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), govern the collection, use, disclosure, and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us (which could include civil and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our operating results and business. In addition, we may obtain health information from third parties (e.g., principal investigators involved in our clinical trials) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, or HIPPA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH. HIPAA generally requires that covered entities (healthcare providers, health plans and healthcare clearinghouses) obtain written authorizations from patients prior to disclosing protected health information of the patient (unless an exception to the authorization requirement applies). If authorization is required and the patient fails to execute an authorization or the authorization fails to contain all required provisions, then we may not be allowed access to and use of the patient's information and our research efforts could be impaired or delayed. Furthermore, use of protected health information that is provided to us pursuant to a valid patient authorization is subject to the limits set forth in the authorization (e.g., for use in research and in submissions to regulatory authorities for product approvals). Among other things, HITECH makes HIPAA's privacy and security standards, as well as the various penalties or failure to comply, directly applicable to "business associates"—independent contractors or agents of covered entities performing certain functions involving the creation or use of protected health information on behalf of a covered entity or providing services to a covered entity. While we do not believe we are a "business associate" under HIPAA, regulatory agencies may disagree.

The collection and use of personal health data in the European Union, presently governed by the provisions of the European Data Protection Directive (95/46/EC), or the EU Directive, as implemented by the European Member States, will be replaced with the General Data Protection Regulation, or GDPR. Currently, the EU Directive establishes a regulatory framework designed to protect the security of personal data collected about residents of the EU and the movement of such personal data across the national borders of the EU Member States. The EU Directive would apply to clinical trial data we may collect about residents of the European Union. GDPR was adopted in 2016 and will become enforceable in the European Union Member States in May 2018. The GDPR will impose many new or additional requirements including, but not limited to, obtaining consent of the individuals to whom the personal data relates, the nature and scope of notifications provided to the individuals, the security and confidentiality of the personal data, data breach notification and using third party processors in connection with the processing of the personal data. Failure to comply with the EU Directive and the GDPR, when effective, could subject us to regulatory sanctions, delays in clinical trials, criminal prosecution and/or civil fines or penalties. Additionally, GDPR creates a direct cause of action by individual data subjects. To comply with the new data protection rules imposed by the GDPR we may be required to use additional human and financial resources to come into and maintain compliance.

Fraud and Abuse Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal prosecution, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and

safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback statute and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Affordable Care Act

In late March 2010, the Federal government enacted the comprehensive health care reform package, the Affordable Care Act (ACA). Among other provisions, the ACA imposes individual and employer health insurance requirements, provides certain insurance subsidies (e.g., premiums and cost sharing), mandates extensive insurance market reforms, creates new health insurance access points (e.g., State and federal-based health insurance exchanges), expands the Medicaid program, promotes research on comparative clinical effectiveness of different technologies and procedures, and makes a number of changes to how products and services will be reimbursed by the Medicare program. Amendments to the Federal False Claims Act under the ACA have made it easier for private parties to bring "qui tam" (whistleblower) lawsuits against companies, under which the whistleblower may be entitled to receive a percentage of any money paid to the government.

Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of the ACA. There is continued uncertainty about the implementation of the ACA, including the potential for further amendments to the ACA and legal challenges to or efforts to repeal the ACA. If the ACA is repealed or further modified, or if implementation of certain aspects of the ACA are delayed, such repeal, modification or delay may materially adversely impact our business, strategies, prospects, operating results or financial condition. We are unable to predict the full impact of any repeal, modification or delay in the implementation of the ACA on us at this time. Due to the substantial regulatory changes that will need to be implemented by CMS and others, and the numerous processes required to implement these reforms, we cannot predict which healthcare initiatives will be implemented at the federal or state level, the timing of any such reforms, or the effect such reforms or any other future legislation or regulation will have on our business.

Designation of and Exclusivity for Qualified Infectious Disease Products

In 2012, Congress passed legislation known as the Generating Antibiotic Incentives Now Act, or GAIN Act. This legislation is designed to encourage the development of antibacterial and antifungal drug products that treat pathogens that cause serious and life-threatening infections. To that end, the law grants an additional five years of marketing exclusivity upon the approval of an NDA for a drug product designated by FDA as a Qualified Infectious Disease Product, or QIDP. Thus, for a QIDP, the periods of five-year new chemical entity exclusivity, three year new clinical investigation exclusivity and seven year orphan drug exclusivity, would become 10 years, eight years, and 12 years, respectively.

A QIDP is defined in the GAIN Act to mean "an antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by —(1) an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens;" or (2) certain "qualifying pathogens." A "qualifying pathogen" is a pathogen that has the potential to pose a serious threat to public health (e.g., resistant gram-positive pathogens, multi-drug resistant gram negative bacteria, multi-drug resistant tuberculosis and *Clostridium difficile*) and that is included in a list established and maintained by FDA. A drug sponsor may request FDA to designate its product as a QIDP any time before the submission of an NDA. FDA must make a QIDP determination within 60 days of the designation request. A product designated as a QIDP will be granted priority review by FDA and can qualify for "fast track" status.

The additional five years of market exclusivity under the GAIN Act for drug products designated by FDA as QIDPs applies only to a drug that is first approved on or after July 9, 2012. Additionally, the five-year exclusivity extension does not apply to: a supplement to an application under Section 505(b) of the FDCA for any QIDP for which an extension is in effect or has expired; a subsequent application submitted with respect to a product approved by FDA for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength; or a product that does not meet the definition of a QIDP under Section 505(g) based upon its approved uses.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of a NDA, plus the time between the submission date of a NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with FDA.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable non-U.S. regulatory authorities before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Pursuant to the European Clinical Trials Directive, a system for the approval of clinical trials in the European Union has been implemented through national legislation of the member states. Under this system, an applicant must obtain approval from the competent national authority of a European Union member state in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial after a competent ethics committee has issued a favorable opinion. Clinical trial application must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the European Clinical Trials Directive and corresponding national laws of the member states and further detailed in applicable guidance documents.

To obtain marketing approval of a drug under European Union regulatory systems, an applicant must submit a marketing authorization application, or MAA, either under a centralized or decentralized procedure.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union member states. The

centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the Committee for Medicinal Products for Human Use, or the CHMP, established at the European Medicines Agency, or EMA, is responsible for conducting the initial assessment of a drug. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to applicants who wish to market a product in various European Union member states where such product has not received marketing approval in any European Union member states before. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one-member state designated by the applicant, known as the reference member state. Under this procedure, an applicant submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the European Commission, whose decision is binding on all member states.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of products approved by FDA and other government authorities. Sales of products will depend, in part, on the extent to which the costs of the products will be covered by third party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on 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.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Third party reimbursement may not be sufficient to maintain price levels high enough to realize an appropriate return on investment in product development.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. For example, the European Union provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Law and Regulation

Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with third party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act imposes civil penalties, and provides for 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 or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the HIPPA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the HITECH and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the federal transparency requirements under the ACA requires manufacturers of drugs to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests and the reported information will be made publicly available on a searchable website; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Human Capital Resources

As of March 22, 2021, we had 20 full-time employees. There are no collective bargaining agreements covering any of our employees.

We believe that our success depends on our ability to attract, develop and retain key personnel. We believe that the skills, experience and industry knowledge of our key employees significantly benefit our operations and performance.

Employee health and safety in the workplace is one of our core values. The COVID-19 pandemic has underscored for us the importance of keeping our employees safe and healthy. In response to the pandemic, we have taken actions aligned with the World Health Organization and the Centers for Disease Control and Prevention in an effort to protect our workforce so they can more safely and effectively perform their work.

Employee levels are managed to align with the pace of business and management believes it has sufficient human capital to operate its business successfully.

Research and Development

For the years ended December 31, 2020 and 2019, we incurred approximately $14.4 million and $11.2 million, respectively, on research and development activities. These expenses include cash and non-cash expenses relating to the development of our clinical and pre-clinical programs, including our anti-infective product candidates, MAT2203 and MAT2501 as well as support and enhancement of our drug delivery technology.

Corporate and Available Information

We were incorporated in Delaware under the name Matinas BioPharma Holdings, Inc. in May 2013. We have two operating subsidiaries: Matinas BioPharma, Inc., a Delaware corporation originally formed on August 12, 2011 as Nereus BioPharma LLC, and Matinas BioPharma Nanotechnologies, Inc., a Delaware corporation originally formed on January 29, 2015 as Aquarius Biotechnologies, Inc.

Our principal executive offices are located at 1545 Route 206 South, Suite 302, Bedminster, New Jersey 07921, and our telephone number is (908) 443-1860. Our website address is www.matinasbiopharma.com. Our website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference into this Annual Report on Form 10-K or any other report we file with or furnish to the SEC.

We make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or the SEC. Our SEC reports can be accessed through the Investors section of our internet website. Further, a copy of this Annual Report on Form 10-K is located at the SEC's Public Reference Rooms at 100 F Street, N.E., Washington, D. C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at http://www.sec.gov.

Item 1A. Risk Factors

An investment in our common stock is speculative and involves a high degree of risk, including a risk of loss of your entire investment. You should carefully consider the risks described below and the other information in this Annual Report before purchasing shares of our common stock. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties may also adversely impair our business operations. If any of the events described in the risk factors below actually occur, our business, financial condition or results of operations could suffer significantly. In such event, the value of our common stock could decline, and you could lose all or a substantial portion of the money that you pay for our common stock.

Summary of Risk Factors

- Our operations, business and financial results have been and could continue to be adversely impacted by the current public health pandemic related to COVID-19.
- We have incurred significant losses since our inception and may never achieve or maintain profitability.
- We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Raising additional capital may cause dilution to stockholders, restrict operations or require us to relinquish rights to our technologies or product candidates.
- Our stockholders may be subject to substantial dilution by the exercise of derivative securities, and by the future issuance of stock to the former stockholders of Aquarius pursuant to the terms of the merger agreement.
- Our operating history to date may make it difficult to evaluate the success of our business and assess our future viability.
- U.S. federal income tax reform could materially affect our tax obligations and effective tax rate.
- We are early in our development efforts, which may not be successful.
- We cannot be certain that our product candidates will receive regulatory approval, without which we cannot market any of our product candidates. Any delay in the approval process will harm our business.
- We depend in part on technology owned or licensed to us by third parties, the loss of which would terminate or delay the further development of our product candidates, injure our reputation or force us to pay higher royalties.
- Clinical drug development involves a lengthy and expensive process and uncertain as to outcome.
- Delays in any aspect of our clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.
- We may not have or be able to obtain sufficient quantities of our products to meet our supply and clinical studies obligations.
- If we are unable to successfully commercialize our products our ability to generate revenue will be limited.
- If our preclinical and clinical studies do not produce positive results, if our clinical trials are delayed or if serious side effects are identified during such studies or trials, we may experience delays, incur additional costs and ultimately be unable to commercialize our product candidates.
- If we cannot enroll enough patients to complete our clinical trials, our business, financial condition and results of operations may be adversely affected.
- If we are unable to establish sales and marketing capabilities, we may not successfully commercialize any of our product candidates.

- If we are unable to file for approval of LYPDISO, MAT2203 or MAT2501 under Section 505(b)(2) of the FDCA or if we are required to generate additional data related to safety and efficacy in order to obtain approval under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.
- We face competition from other biotechnology and pharmaceutical companies.
- Even if we obtain marketing approval for any product candidate, we will be subject to ongoing obligations and continued regulatory review and requirements, which may result in significant additional expense.
- We will not realize the full potential value of LYPDISO if we are not able to successfully partner for its development.
- Future legislation, and/or regulations and policies adopted by the FDA may increase the time and cost required for us to conduct and complete clinical trials.

- Changes in health care law and implementing regulations may have a material adverse effect on us.
- Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.
- If we market our product candidates in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.
- We expect that we will rely on third parties to conduct clinical trials for our product candidates.
- LYPDISO is designed to be a prescription-only omega-3 fatty acid-based medication. If approved, it would be subject to competition from products for which no prescription is required.
- Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives could harm our business.
- We are, and will be, completely dependent on third parties to manufacture LYPDISO.
- Outbreaks of communicable diseases may materially and adversely affect our business, financial condition and results of operations.
- We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from discovering, developing and commercializing our product candidates.
- If we discontinue development of the LNC platform delivery technology, we would be required to return such technology to the former stockholders of Aquarius and we would lose the rights to our lead product candidates.
- It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.
- If we fail to obtain or maintain patent or trade secret protection for our technologies, third parties could use our proprietary information.
- Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.
- We may not be able to obtain or maintain orphan drug or fast-track designation or exclusivity, or priority review for any of our infective product candidates.
- Any breakthrough therapy designation granted by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.
- We will need to increase the size of our organization to grow our business, and we may experience difficulties in managing this growth.
- If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.
- Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.
- We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.
- We are obligated to pay dividends on outstanding shares of our Series B Preferred stock.
- The rights of the holders of common stock may be impaired by the potential issuance of preferred stock.
- A reverse-stock split of our common stock may not have the intended consequences.
- We do not intend to pay dividends on our common stock in the foreseeable future.
- An active public trading market for our common stock may not be sustained.
- Our share price has been and could remain volatile.
- If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.
- We may not be able to maintain an effective system of internal control over financial reporting.
- Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal control requirements.
- Upon dissolution of our company, you may not recoup all or any portion of your investment.
- Anti-takeover provisions of our certificate of incorporation, bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult.
- Stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees could be limited.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

We have incurred significant operating losses in every year since inception and expect to incur net operating losses for the foreseeable future. Our net loss was $22.4 million and $17.4 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $107.5 million. We do not know whether or when we will become profitable. To date, we have not generated any revenues from product sales and have financed our operations through private placements and public offerings of our equity securities and, to a lesser extent, through funding from the Cystic Fibrosis Foundation, or CFF, and the National Institutes of Health, or the NIH. We have devoted substantially all of our financial resources and efforts to the research and development of potential product candidates. We are still in the early stages of development of our product candidates, and we have not completed development of any product candidate. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' deficit and working capital. We anticipate that our expenses will increase substantially if and as we:

- conduct further clinical and preclinical studies of MAT2203 AND MAT2501, our lead LNC product candidates;
- support the conduct of further clinical studies of MAT2203, even if such studies are primarily financed with non-dilutive funding from the NIH;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- require the manufacture of larger quantities of product candidates for clinical development and potentially commercialization;
- maintain, expand and protect our intellectual property portfolio;

- hire additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts and personnel and infrastructure necessary to help us comply with our obligations as a public company.

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue until we are able to obtain marketing approval for, and successfully commercialize, one or more of our product candidates. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling any products for which we may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. We are only in the preliminary stages of most of these activities and have not yet commenced other of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the U.S. Food and Drug Administration, or the FDA, or comparable non-U.S. regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We will need substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct additional preclinical and clinical studies of our ongoing Phase 2 clinical trial of MAT2203 in CM, our preclinical toxicology program for MAT2501, conduct additional preclinical and clinical trials to further validate and expand our LNC platform delivery technology, continue research and development, initiate clinical trials and, if development succeeds, seek regulatory approval of our product candidates. Our expenses could further increase if we initiate new research and preclinical development efforts for other product candidates. In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we expect to incur significant additional costs associated with operating as a public company, particularly as we cease to qualify as an "emerging growth company." Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

We believe that our existing cash, cash equivalents and marketable securities, including restricted cash, of approximately $59.0 million as of December 31, 2020, plus an additional approximately $5.6 million in net proceeds from the sale of our common stock in January 2021, will enable us to fund our operating expenses and capital expenditure requirements into 2024. We have based this estimate on assumptions that may prove to be wrong in the future, and we could use our capital resources sooner than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. Our future capital requirements, both short-term and long-term, will depend on many factors, including:

- the progress, timing, costs and results of our ongoing and planned clinical trials of our product candidates;
- the scope, progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, other product candidates, including MAT2203, any future product candidates based upon our LNC platform delivery technology, including MAT2501, and any preclinical or clinical work done to further validate our LNC platform delivery technology, generally;
- our ability to enter into and the terms and timing of any collaborations, licensing or other arrangements that we may establish;
- the number and development requirements of other product candidates that we pursue;
- the costs, timing and outcome of regulatory review of our product candidates by the FDA and comparable non-U.S. regulatory authorities;

- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the extent to which we acquire or in-license other products and technologies;
- the costs of operating as a public company; and
- the effect of competing technological and market developments.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate product revenues sufficient to achieve profitability, we expect to finance our cash needs through a combination of public or private

equity offerings, debt financings, government or other third-party funding, collaborations and licensing arrangements. We do not have any committed external source of funds other than limited grant funding from the NIH and the CFF. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, your ownership interest may be materially diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. Securing additional financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our stockholders may be subject to substantial dilution by exercises of outstanding options and warrants, conversion of preferred shares and by the future issuance of common stock to the former stockholders of Aquarius pursuant to the terms of the merger agreement.

As of December 31, 2020, we had outstanding options to purchase an aggregate of 22,550,715 shares of our common stock at a weighted average exercise price of $1.26 per share and warrants to purchase an aggregate of 1,327,810 shares of our common stock at a weighted average exercise price of $0.55 per share. In addition, as of December 31, 2020, we had 4,361 shares of Series B Preferred Stock outstanding. Each share of Series B Preferred Stock may be converted into 2,000 shares of common stock upon the earlier of (i) the request of the holder (ii) the first FDA approval of one of our product candidates, (iii) June 19, 2021 and (iv) the consent of the holders of a majority of the Series B then outstanding. The conversion of preferred shares and the exercise of such outstanding options and the warrants, will result in dilution of the value of our shares. In addition, pursuant to the terms of the merger agreement with Matinas BioPharma Nanotechnologies, Inc. (f/k/a Aquarius Biotechnologies, Inc.), we will be required to issue up to an additional 3,000,000 shares of our common stock upon the achievement of certain milestones. The milestone consideration consists of (i) 1,500,000 shares issuable upon the dosing of the first patient in a phase III trial sponsored by us for a product utilizing the LNC platform delivery technology and (ii) 1,500,000 shares issuable upon FDA approval of the first NDA submitted by us for a product utilizing the LNC platform delivery technology.

Our operating history to date may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced active operations in 2013 and our product candidates are in early stages of clinical development. We have not yet demonstrated our ability to successfully obtain regulatory approvals for any of our product candidates, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. Even if we obtain regulatory approval, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter-to-quarter and year-to-year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

U.S. federal income tax reform could materially affect our tax obligations and effective tax rate.

On December 22, 2017, the Tax Cuts and Jobs Act, or the Tax Act, was signed into law, significantly reforming the tax code. The Tax Act, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, limits net operating loss (NOL) deductions, allows for the expensing of capital expenditures, puts into effect the migration from a "worldwide" system of taxation to a territorial system and modifies or repeals many business deductions and credits. The estimated impact of the Tax Act is based on our management's current knowledge and assumptions, and recognized impacts could be materially different from current estimates based on our actual results and our further analysis of the new law.

We continue to examine the impact this tax reform legislation may have on our business. The Tax Act requires complex computations not previously provided in U.S. tax law. As such, the application of accounting guidance for such items is currently uncertain. Further, compliance with the Tax Act and the accounting for such provisions require accumulation of information not previously required or regularly produced. As additional regulatory guidance is issued by the applicable taxing authorities, as accounting treatment is clarified, as we perform additional analysis on the application of the law, and as we refine estimates in calculating the effect, our final analysis, which will be recorded in the period completed, may be different from our current provisional amounts, which could materially affect our tax obligations and effective tax rate.

Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization

We are early in our development efforts, which may not be successful.

We recently completed a head-to-head crossover study of LYPDISO vs. Vascepa and announced topline date in February of 2021. In 2017, we completed two separate Phase 2 clinical trials of MAT2203. Because of the early stage of our development efforts, we are still in the process of determining the overall clinical development path for our current and future product candidates. As a result, the timing and costs of the regulatory paths we will follow, and marketing approvals remain uncertain. Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our early-stage product candidates. The success of LYPDISO, MAT2203, MAT2501 and any other product candidates we may develop will depend on many factors, including the following:

- successful completion of preclinical studies;
- successful enrollment in, and completion of, clinical trials:
- demonstrating safety and efficacy;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates and technologies;

- launching commercial sales of the product candidates, if and when approved, whether alone or selectively in collaboration with others;
- acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payers;
- effectively competing with other therapies;
- a continued acceptable safety profile of the products following approval; and
- enforcing and defending intellectual property rights and claims.

If we do not accomplish one or more of these goals in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would harm our business.

We cannot be certain that LYPDISO, MAT2203 MAT2501 or any other product candidates that we may develop will receive regulatory approval, and without regulatory approval we will not be able to market any of our product candidates. Any delay in the regulatory review or approval of any of our product candidates will materially or adversely harm our business.

We expect to invest most of our capital in the development of our LNC platform delivery technology. Our ability to generate revenue related to product sales, which we do not expect will occur for at least the next several years, if ever, will depend on the successful development and regulatory approval of one or more of our product candidates. All of our product candidates require regulatory review and approval prior to commercialization. Any delays in the regulatory review or approval of our product candidates would delay market launch, increase our cash requirements and result in additional operating losses. This failure to obtain regulatory approvals would prevent our product candidate from being marketed and would have a material and adverse effect on our business.

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Furthermore, this approval process is extremely complex, expensive and uncertain. We may be unable to submit any new drug application, or an NDA, in the United States or any marketing approval application in foreign jurisdictions for any of our products. If we submit an NDA including any amended NDA or supplemental NDA, to the FDA seeking marketing approval for any of our product candidates, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any of these submissions will be accepted for filing and reviewed by the FDA, or that the marketing approval application submissions to any other regulatory authorities will be accepted for filing and review by those authorities. We cannot be certain that we will be able to respond to any regulatory requests during the review period in a timely manner, or at all, without delaying potential regulatory action. We also cannot be certain that any of our product candidates will receive favorable recommendations from any FDA advisory committee or foreign regulatory bodies or be approved for marketing by the FDA or foreign regulatory authorities. In addition, delays in approvals or rejections of marketing applications may be based upon many factors, including regulatory requests for additional analyses, reports, data and studies, regulatory questions regarding data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding such product candidates.

Data obtained from preclinical studies and clinical trials are subject to different interpretations, which could delay, limit or prevent regulatory review or approval of any of our product candidates. Furthermore, regulatory attitudes towards the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, policy changes and agency funding, staffing and leadership. We do not know whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects.

In addition, the environment in which our regulatory submissions may be reviewed changes over time. For example, average review times at the FDA for NDAs have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. Review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes. Moreover, in light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of the U.S. Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of REMS measures that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or may result in approval for a more limited indication than originally sought.

We depend in part on technology owned or licensed to us by third parties, and the loss of access to this technology would terminate or delay the further development of our product candidates, injure our reputation or force us to pay higher royalties.

We rely heavily on the LNC platform delivery technology that we have licensed from Rutgers. The loss of access to this technology could materially impair our business and future viability, and could result in delays in developing, introducing or maintaining our product candidates and formulations until equivalent technology, if available, is identified, licensed and integrated. In addition, any defects in the technology we license could prevent the implementation or impair the functionality of our product candidates or formulation, delay new product or formulation introductions or injure our reputation. If we are required to enter into license agreements with third parties for replacement technology, we could be subject to higher royalty payments.

We may not have or be able to obtain sufficient quantities of our products to meet our supply and clinical studies obligations and our business, financial condition and results of operation may be adversely affected.

To date, we have only developed limited in-house manufacturing capabilities for the LNC platform delivery technology needed for the clinical development our MAT2203 product candidate and preclinical development of our MAT2501 product candidate. If we do not develop a long-term in-house manufacturing capability for our LNC platform product candidates sufficient to produce product for continued development and, if regulatory approval is obtained, then commercialization of these products, we will be dependent on a small number of third-party manufacturers for the manufacture of our product candidates. We may not have long-term agreements with any of these third parties, and if they are unable or unwilling to perform for any reason, we may not be able to locate alternative acceptable manufacturers or formulators or enter into favorable agreements with them. Any inability to acquire sufficient quantities of our products in a timely manner from these third parties could delay clinical trials and prevent us from developing our products in a cost-effective manner or on a timely basis. In addition, manufacturers of our product candidates are subject to cGMP and similar foreign standards and we would not have control over compliance with these regulations by our manufacturers. If one of our contract manufacturers fails to maintain compliance, the production of our products could be interrupted, resulting in delays and additional costs. In addition, if the facilities of such manufacturers do not pass a pre-approval or post-approval plant inspection, the FDA will not grant approval and may institute restrictions on the marketing or sale of our products.

We may be reliant on third party manufactures and suppliers to meet the demands of our clinical supplies. Delays in receipt of materials, scheduling, release, custom's control, and regulatory compliance issues may adversely impact our ability to initiate, maintain, or complete clinical trials that we are sponsoring. Commercial manufacturing and supply agreements have not been established. Issues arising from scale-up, environmental controls, public health crises, such as pandemics and epidemics, equipment requirements, or other factors, may have an adverse impact on our ability to manufacture our product candidates.

Even if we obtain regulatory approval for our product candidates, if we are unable to successfully commercialize our products, it will limit our ability to generate revenue and will materially adversely affect our business, financial condition and results of operations.

Even if we obtain regulatory approval for our product candidates, our long-term viability and growth depend on the successful commercialization of products which lead to revenue and profits. Pharmaceutical product development is an expensive, high risk, lengthy, complicated, resource intensive process. In order to succeed, among other things, we must be able to:

- identify potential drug product candidates;
- design and conduct appropriate laboratory, preclinical and other research;
- submit for and receive regulatory approval to perform clinical studies;
- design and conduct appropriate preclinical and clinical studies according to good laboratory and good clinical practices;
- select and recruit clinical investigators;
- select and recruit subjects for our studies;
- collect, analyze and correctly interpret the data from our studies;
- submit for and receive regulatory approvals for marketing; and
- manufacture the drug product candidates according to cGMP.

The development program with respect to any given product will take many years and thus delay our ability to generate profits. In addition, potential products that appear promising at early stages of development may fail for a number of reasons, including the possibility that the products may require significant additional testing or turn out to be unsafe, ineffective, too difficult or expensive to develop or manufacture, too difficult to administer, or unstable. Failure to successfully commercialize our products will adversely affect our business, financial condition and results of operations.

If our preclinical and clinical studies do not produce positive results, if our clinical trials are delayed or if serious side effects are identified during such studies or trials, we may experience delays, incur additional costs and ultimately be unable to commercialize our product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct, generally at our own expense, extensive preclinical tests to demonstrate the safety of our product candidates in animals, and clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Preclinical and clinical testing is expensive, difficult to design and implement and can take many years to complete. A failure of one or more of our preclinical studies or clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of, preclinical testing and the clinical trial process that could delay or prevent our ability to obtain regulatory approval or commercialize our product candidates, including:

- our preclinical tests or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials or we may abandon projects that we expect to be promising;
- regulators or institutional review boards may not authorize us to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- conditions imposed on us by the FDA or any non-U.S. regulatory authority regarding the scope or design of our clinical trials may require us to resubmit our clinical trial protocols to institutional review boards for re-inspection due to changes in the regulatory environment;
- the number of patients required for our clinical trials may be larger than we anticipate, or participants may drop out of our clinical trials at a higher rate than we anticipate;
- our third-party contractors or clinical investigators may fail to comply with regulatory requirements or fail to meet their contractual obligations to us in a timely manner;
- we might have to suspend or terminate one or more of our clinical trials if we, the regulators or the institutional review boards determine that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we hold, suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- the cost of our clinical trials may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct our clinical trials may be insufficient or inadequate or we may not be able to reach agreements on acceptable terms with prospective clinical research organizations; and
- the effects of our product candidates may not be the desired effects or may include undesirable side effects or the product candidates may have other unexpected characteristics.

In addition, if we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete our clinical trials or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining, or may not be able to obtain, marketing approval for one or more of our product candidates;
- obtain approval for indications that are not as broad as intended or entirely different than those indications for which we sought approval; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or approvals. We do not know whether any preclinical tests or clinical trials will be initiated

as planned, will need to be restructured or will be completed on schedule, if at all. Significant preclinical or clinical trial delays also could shorten the patent protection period during which we may have the exclusive right to commercialize our product candidates. Such delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products or product candidates.

If we cannot enroll enough patients to complete our clinical trials, such failure may adversely affect our business, financial condition and results of operations.

The completion rate of clinical studies of our products is dependent on, among other factors, the patient enrollment rate. Patient enrollment is a function of many factors, including:

- investigator identification and recruitment;
- regulatory approvals to initiate study sites;
- patient population size;
- the nature of the protocol to be used in the trial;
- patient proximity to clinical sites;
- eligibility criteria for the study;
- competition from other companies' clinical studies for the same patient population; and
- ability to obtain comparator drug/device.

We believe our procedures for enrolling patients have been appropriate; however, delays in patient enrollment would increase costs and delay ultimate commercialization and sales, if any, of our products. Such delays could materially adversely affect our business, financial condition and results of operations.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our anti-infective product candidates.

We have sought orphan drug designation for MAT2203 and MAT2501 in the United States and may seek additional orphan drug designation for other product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States. Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same indication for that drug during that time period. For a product that obtains orphan drug designation on the basis of a plausible hypothesis that it is clinically superior to the same drug that is already approved for the same indication, in order to obtain orphan drug exclusivity upon approval, clinical superiority of such product to this same drug that is already approved for the same orphan indication must be demonstrated. The exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the 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.

We cannot assure you that the application for orphan drug designation of MAT2203, or any future application with respect to any other product candidate, will be granted. If we are unable to obtain orphan drug designation in the United States, we will not be eligible to obtain the period of market exclusivity that could result from orphan drug designation or be afforded the financial incentives associated with orphan drug designation. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve 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, more effective or makes a major contribution to patient care.

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 MAT2203 for the treatment of invasive candidiasis, the treatment of aspergillosis, the prevention of invasive fungal infections due to immunosuppressive therapy and the treatment of cryptococcosis and 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 if we do receive Fast Track designation or priority review, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program.

Any breakthrough therapy designation granted by the FDA for our product candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek a breakthrough therapy designation for some of our product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for accelerated approval if the relevant criteria are met.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Designation of our product candidates as qualified infectious disease products is not assured and, in any event, even if granted, may not actually lead to a faster development or regulatory review, and would not assure FDA approval of our product candidates.

We have received a qualified infectious disease product, or QIDP, designation for MAT2203 and MAT2501 for certain indications and we may be eligible for designation of

certain of our product candidates as QIDPs. A QIDP is "an antibacterial or antifungal drug intended to treat serious or life-threatening infections, including those caused by an antibacterial or antifungal resistant pathogen, including novel or emerging infectious pathogens or certain "qualifying pathogens." A product designated as a QIDP will be granted priority review by the FDA and may qualify for "fast track" status. Upon the approval of an NDA for a drug product designated by the FDA as a QIDP, the product is granted a period of five years of regulatory exclusivity in addition to any other period of regulatory exclusivity for which the product is eligible. The FDA has broad discretion whether or not to grant these designations, so even if we believe a particular product candidate is eligible for such designation or status, the FDA could decide not to grant it. Moreover, even if we do receive such a designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures and there is no assurance that our product candidate, even if determined to be a QIDP, will be approved by the FDA.

If we are unsuccessful in identifying and developing additional product candidates, our potential for growth may be impaired.

Even if we receive regulatory approval for LYPDISO, MAT2203, MAT2501 or any other product candidates we may develop, we still may not be able to successfully commercialize such products and the revenue that we generate from its sales, if any, may be limited.

If approved for marketing, the commercial success of LYPDISO, MAT2203, MAT2501 or any other product candidates we may develop will depend upon its acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of LYPDISO, MAT2203, MAT2501 or such other product candidate will depend on a number of factors, including:

- demonstration of clinical safety and efficacy of such product candidate;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse effects;
- the willingness of physicians to prescribe such product candidates and of the target patient population to try new therapies;
- pricing and cost-effectiveness;
- the inclusion or omission of such product candidate in applicable treatment guidelines;
- the effectiveness of our or any future collaborators' sales and marketing strategies;
- limitations or warnings contained in FDA approved labeling;
- our ability to obtain and maintain sufficient third-party coverage or reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third-party payors; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage or reimbursement.

If LYPDISO, MAT2203, MAT2501 or any other product candidates we may develop is approved but does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third-party payors on the benefits of such product candidate may require significant resources and may never be successful.

In addition, even if we obtain regulatory approvals, the timing or scope of any approvals may prohibit or reduce our ability to commercialize such product candidate successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render such product candidate not commercially viable. For example, regulatory authorities may approve such product candidate for fewer or more limited indications than we request, may not approve the price we intend to charge for such product candidate, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve such product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA may place conditions on approvals including potential requirements or risk management plans and the requirement for a Risk Evaluation and Mitigation Strategy ("REMS") to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS; the FDA will not approve the NDA without an approved REMS, if required. A REMS 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. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of such product candidate. Moreover, product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of such product candidate.

We currently have no sales and marketing organization. If we are unable to establish satisfactory sales and marketing capabilities, we may not successfully commercialize any of our product candidates, if regulatory approval is obtained.

At present, we have no sales or marketing personnel. In order to commercialize products that are approved for commercial sales, we must either develop a sales and marketing infrastructure or collaborate with third parties that have such commercial infrastructure. If we elect to develop our own sales and marketing organization, we do not intend to begin to hire sales and marketing personnel until the time of NDA submission to the FDA at the earliest, and we do not intend to establish our own sales organization in the United States until shortly prior to FDA approval of LYPDISO, MAT2203, MAT2501 or any of our other product candidates.

We may not be able to establish a direct sales force in a cost-effective manner or realize a positive return on this investment. In addition, we will have to compete with established and well-funded pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel. Factors that may inhibit our efforts to commercialize LYPDISO, MAT2203, MAT2501 or any of our other product candidates in the United States without strategic partners or licensees include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty successfully commercializing LYPDISO, MAT2203, MAT2501 or any other product candidates we may develop, which

would adversely affect our business, operating results and financial condition. Outside the United States, we may commercialize our product candidates by entering into collaboration agreements with pharmaceutical partners. We may not be able to enter into such agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties

If we are unable to file for approval of LYPDISO, MAT2203 or MAT2501 under Section 505(b)(2) of the FDCA or if we are required to generate additional data related to safety and efficacy in order to obtain approval under Section 505(b)(2), we may be unable to meet our anticipated development and commercialization timelines.

Our current plans for filing the NDAs for LYPDISO, MAT2203 and MAT2501 include efforts to minimize the data we will be required to generate in order to obtain marketing approval for this product candidate and therefore reduce the development time. Based upon written feedback received from the FDA in 2014 and written and verbal FDA feedback in August 2020, we believe this approach will create the opportunity for us to leverage existing data developed with certain existing omega-3 fatty acids to create a streamlined approach to potential approval for LYPDISO for the treatment of SHTG and potentially other indications. Likewise, we intend to rely on the history of efficacy of amphotericin B, and although we met with the FDA in the first half of 2019 to discuss our development plans for MAT2203, there is no assurance we will satisfy FDA's requirements for approval of MAT2203 under a 505(b)(2) pathway. We have not yet met with FDA to discuss the regulatory pathway for MAT2501. The timelines for filing and review of our NDAs for LYPDISO, MAT2203 and MAT2501 are based on our plan to submit these NDAs under Section 505(b)(2) of the FDCA, which would enable us to rely in part on data in the public domain or elsewhere. We have not yet filed an NDA under Section 505(b)(2) for any product candidate. Depending on the data that may be required by the FDA for approval, some of the data may be related to products already approved by the FDA. If the data relied upon is related to products already approved by the FDA and covered by third-party patents we would be required to certify that we do not infringe the listed patents or that such patents are invalid or unenforceable. As a result of the certification, the third-party would have 45 days from notification of our certification to initiate an action against us.

In the event that an action is brought in response to such a certification, the approval of our NDA could be subject to a stay of up to 30 months or more while we defend against such a suit. Approval of our product candidates under Section 505(b)(2) may therefore be delayed until patent exclusivity expires or until we successfully challenge the applicability of those patents to our product candidates. Alternatively, we may elect to generate sufficient additional clinical data so that we no longer rely on data which triggers a potential stay of the approval of our product candidates. Even if no exclusivity periods apply to our applications under Section 505(b)(2), the FDA has broad discretion to require us to generate additional data on the safety and efficacy of our product candidates to supplement third-party data on which we may be permitted to rely. In either event, we could be required, before obtaining marketing approval for any of our product candidates, to conduct substantial new research and development activities beyond those we currently plan to engage in order to obtain approval of our product candidates. Such additional new research and development activities would be costly and time consuming.

We may not be able to realize a shortened development timeline for any of our product candidates, and the FDA may not approve our NDA based on their review of the submitted data. If our desired reference-listed drug containing products are withdrawn from the market by the FDA for any safety reason, we may not be able to reference such products to support a 505(b)(2) NDA for our product candidates, and we may need to fulfill the more extensive requirements of Section 505(b)(1). If we are required to generate additional data to support approval, we may be unable to meet our anticipated development and commercialization timelines, may be unable to generate the additional data at a reasonable cost, or at all, and may be unable to obtain marketing approval of our lead product candidates.

We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors in a number of jurisdictions, many of which have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Established competitors may invest heavily to quickly discover and develop novel compounds that could make LYPDISO, MAT2203, MAT2501 or any other product candidates we may develop obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, which could force us to lower prices or result in reduced sales, particularly those products that have been marketed by third parties for many years and are well accepted by physicians, patients and payers. In addition, new products developed by others could emerge as competitors to LYPDISO, MAT2203, MAT2501 or any of our other product candidates. If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will suffer.

Further, although we believe that our proprietary LNC platform delivery technology, experience and knowledge in our areas of focus provide us with competitive advantages, potential competitors for MAT2203 could reduce our commercial opportunities.

Even if we obtain marketing approval for LYPDISO, MAT2203, MAT2501 or any other product candidates that we may develop, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates could be subject to labeling and other restrictions and withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our future products.

Even if we obtain United States regulatory approval of LYPDISO, MAT2203, MAT2501 or any other product candidates that we may develop, FDA may still impose significant restrictions on its indicated uses or marketing or the conditions of approval or impose ongoing requirements for potentially costly and time-consuming post-approval studies, and post-market surveillance to monitor safety and efficacy. Our future products will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post-market information. These requirements include registration with FDA, as well as continued compliance with current Good Clinical Practices regulations, or cGCPs, for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continuous review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, cGMP, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents.

FDA has the authority to require a REMS, as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria or requiring patient testing, monitoring and/or enrollment in a registry.

With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U.S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute, U.S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing, and scientific/educational grant programs. If we participate in the U.S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U.S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U.S. federal and state consumer protection and unfair competition laws. Similar requirements exist in many of these areas in other countries.

In addition, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. FDA strictly regulates the

promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by FDA as reflected in the product's approved labeling. If we receive marketing approval for our product candidates, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability and government fines. FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions, including revocation of its marketing approval. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed.

If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- issuance of warning letters or untitled letters;
- clinical holds;
- injunctions or the imposition of civil or criminal penalties or monetary fines;
- suspension or withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or
- product seizure or detention or refusal to permit the import or export of product.

The occurrence of any event or penalty described above may inhibit our ability to commercialize LYPDISO, MAT2203, MAT2501 or any of our other product candidates and generate revenue. Adverse regulatory action, whether pre- or post-approval, can also potentially lead to product liability claims and increase our product liability exposure.

We are in the process of evaluating potential next steps in the development of LYPDISO.

Based on the results of our ENANCE-IT study for LYPDISO, and given the significant time and cost associated with cardiovascular outcomes clinical trials, we have initiated a process to identify a partner to advance development of LYPDISO and have allocated resources away from a Phase 3 program for LYPDISO. However, there is no guarantee that we will identify a suitable partner for LYPDISO or that we will be able to enter into a partnering agreement on favorable terms. In the event that we do not identify a suitable partner, enter into a partnering agreement on favorable terms, or if a potential partner fails to satisfy its obligations to develop and commercialize LIPDOSO, we may never realize the full or any value from LYPDISO.

Future legislation, and/or regulations and policies adopted by the FDA may increase the time and cost required for us to conduct and complete clinical trials of LYPDISO, MAT2203, MAT2501 and any other product candidates that we may develop.

FDA has established regulations to govern the drug development and approval process, as have foreign regulatory authorities. The policies of FDA and other regulatory authorities may change, and additional laws or government regulations may be promulgated that could prevent, limit, delay but also accelerate regulatory review of our product candidates. For example, in December 2016, the Cures Act was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and spur innovation, but all of its provisions have yet to be implemented. Among other things, the Cures Act provides a new "limited population" pathway for certain antibacterial and antifungal drugs, or LPAD, but FDA has not issued final guidance regarding the LPAD yet. Additionally, in August 2017, FDA issued final guidance setting forth its current thinking with respect to development programs and clinical trial designs for antibacterial drugs to treat serous bacterial diseases in patients with an unmet medical need. We cannot predict what if any effect the Cures Act or any existing or future guidance from FDA will have on development of our product candidates.

Healthcare legislative or regulatory reform measures, including government restrictions on pricing and reimbursement, may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in the United States, the Patient Protection and Affordable Care Act of 2010 ("ACA") substantially changed the way health care is financed by both governmental and private insurers and significantly affects the pharmaceutical industry. Many provisions of the ACA impact the biopharmaceutical industry, including that in order for a biopharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the drug pricing program under the Public Health Services Act, or PHS. Since its enactment, there have been judicial and Congressional challenges and amendments to certain aspects of ACA. There is continued uncertainty about the implementation of the ACA, including the potential for further amendments to the ACA and legal challenges to or efforts to repeal the ACA.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the now-departed Trump administration proposed numerous prescription drug cost control measures. Similarly, the new Biden administration has made lowering prescription drug prices one of its priorities. The Biden administration has not yet proposed any specific plans, but we expect that these will be forthcoming in the near term. At the state level, legislatures are increasingly 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. Other examples of proposed changes include, but are not limited to, expanding post-approval requirements, changing the Orphan Drug Act, and restricting sales and promotional activities for pharmaceutical products.

We cannot be sure whether additional legislative changes will be enacted, or whether government regulations, guidance or interpretations will be changed, or what the impact of such changes would be on the marketing approvals, sales, pricing, or reimbursement of our drug candidates or products, if any, may be. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. 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.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for our product candidates. We cannot determine how changes in regulations, statutes, policies, or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;

- changes to manufacturing methods;
- recalls, replacements, or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of our product candidates. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition, and results of operations.

Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare or Medicaid data used to calculate these rates. Net prices for products may be reduced by mandatory discounts or rebates required by government health care programs. Such legislation, or similar regulatory changes or relaxation of laws that restrict imports of products from other countries, could reduce the net price we receive for any future marketed products. As a result, our future products might not ultimately be considered cost-effective. We cannot be certain that reimbursement will be available for any of our product candidates. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, any future products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any product candidates that we develop.

Our future growth depends, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend, in part, on our ability to commercialize our product candidates in foreign markets for which we intend to rely on collaborations with third parties. If we commercialize LYPDISO, MAT2203, MAT2501 or any other product candidates that we may develop in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our results of operations.

If we market our product candidates in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.

FDA enforces laws and regulations which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so-called "off label" use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct can subject that company to significant liability. Similarly, industry codes in the EU and other foreign jurisdictions prohibit companies from engaging in off-label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include the U.S. Anti-Kickback Statute, U.S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be

The U.S. Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and

formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the U.S. Anti-Kickback Statute and criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the U.S. Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the U.S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid.

Over the past few years, several pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion that caused claims to be submitted to Medicare or Medicaid for non-covered, off-label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U.S. Anti-Kickback Statute and the U.S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include substantial civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, substantial criminal fines and imprisonment.

We have been and expect to be significantly dependent on our collaborative agreements for the development of MAT2203 and MAT2501, which exposes us to the risk of reliance on the performance of third parties.

In conducting our research and development activities for MAT2203 and MAT2501, we currently rely, and expect to continue to rely, on collaborative agreements with universities, governmental agencies and not-for-profit organizations for both strategic and financial resources. Key among these agreements is our collaboration agreements with the NIH for the development of MAT2203 and our award agreement with the CFF for the development of MAT2501. The loss of, or failure to perform by us or our partners under any applicable agreements or arrangements, or our failure to secure additional agreements for our product candidates, would substantially disrupt or delay our research and development activities, including our in-process and anticipated clinical trials. Any such loss would likely increase our expenses and materially harm our business, financial condition and results of operation.

We expect that we will rely on third parties to conduct clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize LYPDISO, MAT2203, MAT2501 or any other product candidates that we may develop, and our business could be substantially harmed.

We expect to enter into agreements with third-party CROs, or governmental entities like the NIH, to conduct and manage our clinical programs. We rely heavily on these parties for execution of clinical studies for LYPDISO, MAT2203, MAT2501 and our other product candidates and can control only certain and very limited aspects of their activities. Nevertheless, we would be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the NIH or CROs would not relieve us of our regulatory responsibilities. We, the NIH and our CROs would be required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any products in clinical development. The FDA enforces these cGCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or the NIH or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our clinical trials comply with cGCPs. In addition, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. Our failure or the failure of the NIH or our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the NIH or the CROs may not perform all of their obligations under their arrangements with us or in compliance with regulatory requirements. If NIH or the CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of LYPDISO, MAT2203, MAT2501 or any other product candidates that we may develop may be delayed or our development program may be materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs would devote to our program or our product candidates. If we are unable to rely on the clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. As a result of the foregoing, our financial results and the commercial prospects for LYPDISO, MAT2203, MAT2501 and our other product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

LYPDISO is designed to be a prescription-only omega-3 fatty acid-based medication. Omega-3 fatty acid-based products are also marketed by other companies as dietary supplements, which, unlike drugs, are not subject to FDA approval and therefore do not require a prescription and are not subject to pharmaceutical manufacturing standards. As a result, LYPDISO, if approved, would be subject to competition from products for which no prescription is required.

If approved by the regulatory authorities, LYPDISO will be a prescription-only omega-3 fatty acid-based medication. Mixtures of omega-3 fatty acids are naturally occurring substances in various foods, including fatty fish. Omega-3 fatty acids are also marketed as dietary supplements, which may generally be marketed without a lengthy FDA premarket review and approval process and are not subject to prescription. However, unlike prescription drug products, manufacturers of dietary supplements may not make therapeutic claims for their products; dietary supplements may be marketed with claims describing how the product affects the structure or function of the body without premarket approval but may not expressly or implicitly represent that the dietary supplement will diagnose, cure, mitigate, treat, or prevent disease. We believe the exact omega-3 fatty acid composition and pharmaceutical-grade purity of LYPDISO has a superior therapeutic profile to the omega-3 compositions in commercially available dietary supplements. However, we cannot be sure that physicians or consumers will view LYPDISO as superior. To the extent the price of LYPDISO is significantly higher than the prices of commercially available omega-3 fatty acids marketed by other companies as dietary supplements, physicians may recommend these commercial alternatives instead of LYPDISO or patients may elect on their own to take commercially available non-prescription omega-3 fatty acids. Either of these outcomes may adversely impact our results of operations by limiting product sales and how we price our product, thereby limiting the revenue we receive from sales of LYPDISO

We are, and will be, completely dependent on third parties to manufacture our product candidates, and our commercialization of efforts could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of any product candidate or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredient, or API, in MAT2203, or any of our product candidates, for use in our clinical trials or for commercial product, if any. As a result, we will rely on contract manufacturers throughout the development process and then if and when MAT2203, or any of our product candidates are approved for commercialization. We have not entered into any agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of MAT22203, or any of our product candidates, on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture any of our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs for manufacture of both active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of a product candidate or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market such product candidate , if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We do not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our product candidates , delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market any of our product candidates .

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished product or should cease doing business with us, we could experience significant interruptions in product supply or may not be able to create a supply of any product candidate at all. Were we to encounter manufacturing issues, our ability to produce a sufficient product supply might be negatively affected. Our inability to coordinate the efforts of our third-party manufacturing partners, or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply any product candidate at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in product supply if we decided to transfer manufacturing to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of our product candidates, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of any product candidate over time. If the commercial-scale manufacturing costs of LYPDISO are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

Outbreaks of communicable diseases may materially and adversely affect our business, financial condition and results of operations.

We face risks related to health epidemics or outbreaks of communicable diseases. The outbreak of communicable diseases, such as COVID-19, have resulted in a widespread health crisis that has adversely affected general commercial activity and the economies and financial markets of many countries. Since some of our business partners are outside of the U.S., in China and other Asian countries, including manufacturing operations for our active pharmaceutical ingredient, an outbreak of communicable diseases in Asia or elsewhere, or the perception that such an outbreak could occur, and the measures taken by the governments of countries affected could adversely affect our business, financial condition or results of operations. For example, an outbreak could significantly disrupt our business by limiting our ability to travel or ship materials within or outside China and forcing temporary closure of facilities that we rely upon.

Risks Relating to Our Intellectual Property Rights and Regulatory Exclusivity

We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from discovering, developing and commercializing our product candidates.

We rely partially upon our LNC platform delivery technology which is licensed to us by Rutgers. We do not own the patents that underly this in-license technology. Our rights to use the technology we license are subject to the negotiation of, continuation of and compliance with the terms of our license agreement with Rutgers. Pursuant to the terms of our license agreement with Rutgers, we control the prosecution, maintenance, or filing of the patents to which we hold licenses, as well as the enforcement of these patents against third parties. However, some of our patents and patent applications were either acquired from another company who acquired those patents and patent applications from yet another company or are licensed from a third party. Thus, these patents and patent applications were not written by us or our attorneys, and we did not have control over the drafting and prosecution of certain of these patents. The former patent owners and our licensors might not have given the same attention to the drafting and prosecution of these patents and applications as we would have if we had been the owners of the patents and applications and had control over the drafting and prosecution. We cannot be certain that drafting and/or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

Our rights to use the technology we license are subject to the validity of the owner's intellectual property rights. Enforcement of our licensed patents or defense or any claims asserting the invalidity of these patents is often subject to the control or cooperation of our licensors. Legal action could be initiated against the owners of the intellectual property that we license and an adverse outcome in such legal action could harm our business because it might prevent such companies or institutions from continuing to license intellectual property that we may need to operate our business. In addition, such licensors may resolve such litigation in a way that benefits them but adversely affects our ability to use the licensed technology for our products.

Certain of our licenses contained in our agreement with Rutgers contain provisions that allow the licensor to terminate the license if (i) we breach any payment obligation or other material provision under the agreement and fail to cure the breach within a fixed time following written notice of termination, (ii) we or any of our affiliates, licensees or sub licensees directly or indirectly challenge the validity, enforceability, or extension of any of the licensed patents or (iii) we declare bankruptcy or dissolve. Our rights under the licenses are subject to our continued compliance with the terms of the license, including the payment of royalties due under the license. Termination of these licenses would prevent us from discovering, developing and commercializing product candidates based on the LNC platform delivery technology, including our lead anti-infective product candidates, MAT2203 and MAT2501. Determining the scope of the license and related royalty obligations can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties' payable pursuant to the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor might attempt to revoke the license. If such an attempt were successful, we

might be barred from discovering, developing and commercializing product candidates based on the LNC platform delivery technology, including our lead anti-infective product candidates.

If we discontinue development of the LNC platform delivery technology, we would be required to return such technology to the former stockholders of Aquarius and we would lose the rights to our lead product candidates.

Under certain circumstances, we will be required to transfer Aquarius' LNC platform delivery technology back to the former shareholders of Aquarius. This transfer would be required under the Merger Agreement in the event the following conditions are met: (i) no milestone events have occurred on or before the two-year anniversary of the effective time of the Aquarius Merger (the "Transfer Date"), (ii) during such period we shall have discontinued efforts to develop or commercialize the LNC platform delivery technology (as conclusively demonstrated by our omission of the LNC platform delivery technology in at least two consecutive royalty, progress and payment reports delivered to Rutgers pursuant to the license agreement entered into between Aquarius and Rutgers) and (iii) as of the Transfer Date, no unresolved indemnification claims for us and our indemnified parties are pending. If the foregoing conditions are met, we would transfer the LNC platform delivery technology to the stockholder representative or to a newly formed entity as directed by the stockholder representative (in either case for the benefit of the former Aquarius stockholders) following receipt of any necessary third-party consents required for the transfer, which we shall use its commercially reasonable efforts to obtain. If we are required to transfer the LNC platform delivery technology back to the former shareholders of Aquarius, we would lose our rights to our lead product candidates, which would have a material and adverse effect on our business.

It is difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights.

Our commercial success will depend, in part, on obtaining and maintaining patent protection for our technologies, products and processes, successfully defending these patents against third-party challenges and successfully enforcing these patents against third party competitors. The patent positions of pharmaceutical companies can be highly uncertain and involve complex legal, scientific and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in interpretations of patent laws may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowable or enforceable in our patents (including patents owned and licensed by us). We currently own or have rights to 33 issued patents relating to our LNC platform delivery technology, as well as pending patent applications for our LNC platform delivery technology that may never be approved by the United States or foreign patent offices. Furthermore, any patents which may eventually be issued from existing patent applications for any of our technologies, may be challenged, invalidated or circumvented by third parties and might not protect us against competitors with similar products or technologies.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights, permit us to gain or keep our competitive advantage, or provide us with any competitive advantage at all. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed by us, or that we will not be involved in interference, opposition or invalidity proceedings before the United States or foreign patent offices.

We also rely on trade secrets to protect technology, especially in cases where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. Typically, research collaborators and scientific advisors have rights to publish data and information in which we may have rights. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Enforcing a claim that a third-party entity illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts are sometimes less willing to protect trade secrets than patents. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If we fail to obtain or maintain patent protection or trade secret protection for our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability.

We may also develop trademarks to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us or our business partners will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use 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 resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks.

Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts.

Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights. Identification of third-party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we may be unaware of third-party patents that may be infringed by commercialization of LYPDISO, MAT2203, MAT2501 or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize LYPDISO, MAT2203 or MAT2501 and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties against us would be time-consuming and may:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to cease or modify our use of the technology and/or develop non-infringing technology; or
- require us to enter into royalty or licensing agreements.

Although no third party has asserted a claim of infringement against us, others may hold proprietary rights that could prevent LYPDISO, MAT2203 or MAT2501 from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to LYPDISO, MAT2203, MAT2501 or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market our current product candidates or any future product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign, LYPDISO, MAT2203, MAT2501or any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing LYPDISO, MAT2203, MAT2501 or a future product candidate, which could harm our business, financial condition and operating results.

We anticipate that competitors may from time to time oppose our efforts to obtain patent protection for new technologies or to submit patented technologies for regulatory approval. Competitors may seek to oppose our patent applications to delay the approval process or to challenge our granted patents, for example, by requesting a reexamination of our patent at the United States Patent and Trademark Office, or the USPTO, or by filing an opposition in a foreign patent office, even if the opposition or challenge has little or no merit. Such proceedings are generally highly technical, expensive and time consuming, and there can be no assurance that such a challenge would not result in the narrowing or complete revocation of any patent of ours that was so challenged.

Moreover, generic companies have received FDA approval of generic versions of Amarin Corporation's Vascepa® (icosapent ethyl), which is made from an omega-3 fatty acid, in the United States. Any generic market entry of a generic prescription omega-3 fatty acid product could limit our U.S. sales, which would have a significant adverse impact on our business and results of operations. In addition, even if a competitor's effort to introduce a generic product is ultimately unsuccessful, the perception that such development is in progress and/or news related to such progress could materially affect the perceived value of our company and our stock price.

General Company-Related Risks

We will need to increase the size of our organization to grow our business, and we may experience difficulties in managing this growth.

We currently have only twenty employees as of March 22, 2021. As our development and commercialization plans and strategies develop, we will need to expand the size of our employee base for managerial, development, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize our product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees would adversely impact our business prospects.

If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. In addition, the loss of the services of certain key employees, including Jerome D. Jabbour, our Chief Executive Officer and President, and James J. Ferguson, our Chief Medical Officer, would adversely impact our business prospects.

Our ability to compete in the highly competitive pharmaceutical industry depends in large part upon our ability to attract highly qualified managerial, scientific and medical personnel. In order to induce valuable employees to remain with us, we intend to provide employees with stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that we will not be able to control and may at any time be insufficient to counteract more lucrative offers from other companies.

Other pharmaceutical companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles, and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize product candidates would be limited.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face a potential risk of product liability as a result of the clinical testing of LYPDISO, MAT2203, MAT2501 or any future product candidates and will face an even greater risk if we commercialize LYPDISO, MAT2203, MAT2501 or any other future product. For example, we may be sued if any product we develop or any material that we use in our products allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of LYPDISO, MAT2203 or MAT2501. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for LYPDISO, MAT2203, MAT2501 or any future products that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize our product candidates; and
- a decline in our stock price.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We have obtained product liability insurance covering our clinical trials in the amount of greater than or equal to $5 million in the aggregate. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage or disruption from computer viruses, software bugs, unauthorized access, natural disasters, terrorism, war, and telecommunication, equipment and electrical failures. While we have not, to our knowledge, experienced any significant system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure or theft of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed, our competitive position could be compromised, or our business reputation could be harmed.

We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

Risks related to our Securities

Pursuant to the terms of our Series A Preferred Stock, we may be obligated to pay significant royalties.

Pursuant to the terms of the Certificate of Designations of Preferences, Rights and Limitations (the "Certificate of Designations") for our Series A Preferred Stock, we are required to pay royalties of up to $35 million per year. If and when we obtain FDA or EMA approval of MAT2203 and/or MAT2501, which we do not expect to occur before 2023, if ever, and/or if we generate sales of such products, or we receive any proceeds from the licensing or other disposition of MAT2203 or MAT2501, we are required to pay to the holders of our Series A Preferred Stock, subject to certain vesting requirements, in aggregate, a royalty equal to (i) 4.5% of Net Sales (as defined in the Certificate of Designations), subject in all cases to a cap of $25 million per calendar year, and (ii) 7.5% of Licensing Proceeds (as defined in the Certificate of Designations), subject in all cases to a cap of $10 million per calendar year. The Royalty Payment Rights will expire when the patents covering the applicable product expire, which is currently expected to be in 2033.

We are obligated to pay dividends on outstanding shares of our preferred stock.

Holders of our Series B Preferred Stock will be entitled to receive dividends equaling a number of shares of common stock equal to 20% of the shares of common stock underlying the Series B Preferred then held by such holder on June 19, 2021.

The payment of such dividends will result in additional dilution to our holders of our common stock.

The rights of the holders of common stock may be impaired by the potential issuance of preferred stock.

Our articles of incorporation give our board of directors the ability to designate and issue preferred stock in one or more series. As a result, the board of directors may, without stockholder approval, issue new series of preferred stock with voting, dividend, conversion, liquidation or other rights which could adversely affect the relative voting power and equity interest of the holders of common stock. Additional issuances of preferred stock, which could be issued with the right to more than one vote per share, could have the effect of discouraging, delaying or preventing a change of control of us. The possible impact on takeover attempts could adversely affect the price of our common stock. Although we have no present intention to designate any new series, or issue any shares, of preferred stock, we may do so in the future.

A reverse-stock split of our common stock may not have the intended consequences.

On January 26, 2021, our shareholders approved an amendment to our Certificate of Incorporation to effect a reverse stock split at a ratio in the range of 1-for-2 to 1-for-15, to be determined at the discretion of the Board. We believe that the reverse stock split may result in an increase to the market price of our common stock, enhance the appeal of our common stock to the financial community, improve the trading liquidity of our common stock, make it possible for us to "up-list" our common stock to a higher tier stock exchange, and make us eligible for inclusion on certain biotechnology and pharmaceutical trading indices and exchange-traded funds.

However, we cannot assure you that the reverse stock split, if implemented, will result in any anticipated benefits, including an increase of the market price of our common stock in proportion to the reduction in the number of shares of our common stock outstanding. Moreover, a reverse-stock split may have the effect of decreasing our overall market value. There can be no assurance that the reverse stock split will result in a per share price that will attract institutional investors or investment funds or that such share price will satisfy the investing guidelines of institutional investors or investment funds or improve the trading liquidity of our common stock. Further, because implementation of the reverse stock split would not change the total number of shares of our common stock authorized for issuance, the number of shares of our common stock available for issuance following the implementation of the reverse stock split would increase to the extent the reverse stock split reduces the number of outstanding shares of our common stock. Such available shares may be used for future corporate purposes, including future acquisitions, investment opportunities, the establishment of collaboration or other strategic agreements, capital raising transactions involving equity or convertible debt securities, future at the market offerings of common stock, or issuance under current or future employee equity plans, and the issuance of equity securities in connection with such transactions may result in potentially significant dilution of our current stockholders' ownership interests in us.

We do not intend to pay dividends on our common stock in the foreseeable future.

The Board of Directors will determine, in its sole discretion, our dividend policy after considering our financial condition, results of operations and capital requirements, as well as other factors. No dividends may be declared or paid on our common stock, unless a dividend, payable in the same consideration or manner, is simultaneously declared or paid, as the case may be, on the shares of Series B Preferred Stock. We do not anticipate paying cash dividends on our common stock in the foreseeable future and you should not invest in us with the anticipation of receiving dividend income.

An active public trading market for our common stock may not be sustained.

Although our common stock was listed on the NYSE American, the market for our shares has demonstrated varying levels of trading activity, and we cannot assure you that an active trading market will be sustained. A lack of an active market may impair your ability to sell shares of our common stock at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the price of shares of our common stock. An inactive market may also impair our ability to raise capital by selling shares of capital stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration.

Our share price has been and could remain volatile.

The market price of our common stock has historically experienced and may continue to experience significant volatility. Our progress in developing our product candidates,

the impact of government regulations on our products and industry, the potential sale of a large volume of our common stock by stockholders, our quarterly operating results, changes in general conditions in the economy or the financial markets and other developments affecting us or our competitors could cause the market price of our common stock to fluctuate substantially with significant market losses. If our stockholders sell a substantial number of shares of common stock, especially if those sales are made during a short period of time, those sales could adversely affect the market price of our common stock and could impair our ability to raise capital. In addition, in recent years, the stock market has experienced significant price and volume fluctuations. This volatility has affected the market prices of securities issued by many companies for reasons unrelated to their operating performance and may adversely affect the price of our common stock. In addition, we could be subject to a securities class action litigation as a result of volatility in the price of our stock, which could result in substantial costs and diversion of management's attention and resources and could harm our stock price, business, prospects, results of operations and financial condition.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. Our research coverage by industry and financial analysts is currently limited. Even if our analyst coverage increases, if one or more of the analysts who cover us downgrade our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

If we are unable to maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our common stock could be adversely affected.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of SOX, or Section 404, requires that we evaluate and determine the effectiveness of our internal controls over financial reporting and provide a management report on internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

Management assessed the effectiveness of our internal control over financial reporting based on criteria established in "Internal Control—Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has concluded as of December 31, 2020, our internal control over financial reporting was not effective, as management identified a deficiency in internal control over financial reporting that was determined to be a material weakness, and the auditor's report included an adverse opinion.

We did not maintain an effective control environment over the internal control activities to ensure the processing of and reporting of transactions are complete, accurate and timely. Specifically, we have not designed and implemented a sufficient level of formal financial reporting and operating policies and procedures that define how transactions should be initiated, processed, recorded and reported, including presentation and disclosure in the consolidated financial statements.

If our steps are insufficient to successfully remediate the material weakness and otherwise establish and maintain an effective system of internal control over financial reporting, the reliability of our financial reporting, investor confidence in us and the value of our common stock could be materially and adversely affected. Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

Moreover, we do not expect that disclosure controls or internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Failure of our control systems to prevent error or fraud could materially adversely impact us.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal control requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with applicable provisions of the Sarbanes-Oxley Act, and the related rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

We rely on consultants to perform certain of our accounting and financial reporting functions. We will need to hire additional finance personnel and build our financial infrastructure as we comply with public company reporting requirements, including complying with the applicable requirements of Section 404 of the Sarbanes-Oxley Act. We may be unable to do so on a timely basis.

Upon dissolution of our company, you may not recoup all or any portion of your investment.

In the event of a liquidation, dissolution or winding-up of our company, whether voluntary or involuntary, the proceeds and/or assets of our company remaining after giving effect to such transaction, and the payment of all of our debts and liabilities will be distributed first to the holders of our preferred stock and thereafter to the stockholders of common stock (including the holders of our preferred stock on an "as converted" basis) on a pro rata basis. There can be no assurance that we will have available assets to pay to the holders of common stock, or any amounts, upon such a liquidation, dissolution or winding-up of our Company. In this event, you could lose some or all of your investment.

Our certificate of incorporation allows for our board to create new series of preferred stock without further approval by our stockholders, which could adversely affect the rights of the holders of our common stock.

Our board of directors has the authority to fix and determine the relative rights and preferences of preferred stock. We anticipate that our board of directors will have the authority to issue up to 8,392,000 additional shares of our preferred stock without further stockholder approval. As a result, our board of directors could authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, prior to the redemption of our common stock. In addition, our board of directors could authorize the issuance of a series of preferred stock that has greater voting power than our common stock or that is convertible into our common stock, which could decrease the relative voting power of our common stock or result in dilution to our existing stockholders.

Anti-takeover provisions of our certificate of incorporation, our bylaws and Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove the current members of our board and management.

Certain provisions of our amended and restated certificate of incorporation and bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your Shares. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove members of our board of directors. These provisions also could limit the price that investors might be willing to pay in the future for our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions, among other things:

- they provide that special meetings of stockholders may be called only by the board of directors, President or our Chairman of the Board of Directors, or at the request in writing by stockholders of record owning at least fifty (50%) percent of the issued and outstanding voting shares of common stock;

- they do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in our board of directors; and

- they allow us to issue, without stockholder approval, up to 10,000,000 shares of preferred stock (of which up to 8,392,000 shares remain available for issuance) that could adversely affect the rights and powers of the holders of our common stock.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or DGCL, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America will be the exclusive forums 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 directors, officers or employees.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. Our certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. For example, stockholders who do bring a claim in the Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near the State of Delaware. The Court of Chancery and federal district courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. Some companies that adopted a similar federal district court forum selection provision are currently subject to a suit in the Chancery Court of Delaware by stockholders who assert that the provision is not enforceable. If a court were to find either choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. For example, the Court of Chancery of the State of Delaware recently determined that the exclusive forum provision of federal district courts of the United States of America for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. As a result of this decision, we do not currently intend to enforce the federal forum selection provision in our certificate of incorporation, unless the decision is reversed on appeal. However, if the decision is reviewed on appeal and ultimately overturned by the Delaware Supreme Court, we would enforce the federal district court exclusive forum provision.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As a result of our merger with Aquarius Biotechnologies, Inc., our ability to utilize our U.S. federal net operating loss, carryforwards and U.S. federal tax credits may be limited under Sections 382 of the Internal Revenue Code of 1986, as amended. The limitations apply if an "ownership change," as defined by Section 382 and Section 383, occurs. Generally, an ownership change occurs if the percentage of the value of the stock that is owned by one or more direct or indirect "five percent shareholders" increases by more than 50 percentage points over their lowest ownership percentage at any time during the applicable testing period (typically three years). In addition, future changes in our stock ownership, which may be outside of our control, may trigger an "ownership change" and, consequently, Section 382 and Section 383 limitations. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other tax attributes to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, the Tax Act, among other things, imposes significant additional limitations on the deductibility of interest and limits net operating loss (NOL) deductions to 80% of net taxable income for losses arising in taxable years beginning after December 31, 2017.

Item 1B. Unresolved Staff comments

None.

Item 2. Properties

Facilities

Our administrative offices consist of approximately 5,900 square feet of office space in Bedminster, NJ that we occupy under a lease that expires in May 2021. On September 23, 2020, we entered into a lease amendment which provides for an additional 3,034 square feet of space extends the term of the lease for seven years from the date the amendment becomes effective, which is anticipated to be in the second quarter of 2021. We also lease laboratory space approximating 14,000 square feet in Bridgewater, NJ, that expires in 2027.

Item 3. Legal Proceedings

We are not currently a party to any legal proceedings, and we are not aware of any claims or actions pending or threatened against us. In the future, we might 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 Registrant's Common Equity, Related Stockholder Matters And Issuer Purchases Of Equity Securities

Market Price and Dividend Information

Our common stock is quoted on the NYSE American under the symbol "MTNB". The following table sets forth the high and low sales price for our common stock for each full quarterly period within the last two fiscal years, as reported by the NYSE American.

	Fiscal Year 2019	
	High	Low
First Quarter	$ 1.41	$ 0.60
Second Quarter	$ 1.11	$ 0.79
Third Quarter	$ 0.76	$ 0.59
Fourth Quarter	$ 2.27	$ 0.63

	Fiscal Year 2020	
	High	Low
First Quarter	$ 2.31	$ 0.60
Second Quarter	$ 0.92	$ 0.52
Third Quarter	$ 0.96	$ 0.67
Fourth Quarter	$ 1.47	$ 0.76

Holders

On March 12, 2021, the closing sale price of our common stock, as reported by the NYSE American, was $1.20 per share and we had approximately 123 record holders of our common stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies. VStock Transfer, LLC is the transfer agent and registrar for our common stock.

Dividends

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

Recent Sales of Unregistered Securities

None.

Repurchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our registered securities during the period covered by this Annual Report.

Item 6. Selected Financial Data

Per §229.301 of Regulation S-K, the Company, designated a Smaller Reporting Company as defined in Section §229.10(f)(1) of Regulation S-K, is not required to provide selected financial data. Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to help the reader understand the results of operations and financial condition of the Company and should be read in conjunction with our audited consolidated financial statements and notes thereto for the year ended December 31, 2020.

Item 7. Management's Discussion And Analysis Of Financial Condition And Results Of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and financing needs, includes forward-looking statements that involve risks and uncertainties and should be read together with the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Annual Report and in other reports we file with the Securities and Exchange Commission, particularly those under "Risk Factors." Dollars in tabular format are presented in thousands, except per share data, or otherwise indicated.

Overview

We are focused on creating value through improving the intracellular delivery of critical therapeutics through our paradigm-changing lipid nanocrystal (LNC) drug delivery platform and its application to overcome current challenges in safely and effectively delivering small molecules, nucleic acids, gene therapies, proteins/peptides, and vaccines. We are also focused on creating value through finding a partner to continue the development of LYPDISO, our proprietary, next-generation prescription omega-3 drug, which we believe is differentiated from all other prescription omega-3 products and positioned to potentially demonstrate superior cardioprotective effects.

Key elements of our strategy include:

- Advancing our clinical stage assets based on our LNC platform delivery technology and continuing to expand utilization of this promising technology into areas of innovative medicine. .

- Delivering efficacy data for MAT2203 in the EnACT study for the treatment of cryptococcal meningitis, which would highlight the safety and efficacy of this promising drug, while highlighting the ability of our LNC platform technology to deliver potent medicines across the blood-brain barrier following oral administration.

- Progressing the development of MAT2501 through extensive preclinical toxicology and efficacy studies in NTM infections and completing a single ascending dose pharmacokinetic study in healthy volunteers later in 2021, all with the financial support of the Cystic Fibrosis Foundation.

- Expanding the application of our LNC platform delivery technology through collaborations with sophisticated and well-resourced biotech and pharmaceutical companies in areas of innovative medicine.

We have incurred losses for each period from inception. Our net loss was approximately $22.4 million and $17.4 million for the fiscal years ended December 31, 2020 and 2019, respectively. We expect to incur significant expenses and operating losses over the next several years. Accordingly, we will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity offerings, debt financings, government or other third-party funding, collaborations and licensing arrangements. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would impact our going concern and would have a negative impact on our financial condition and our ability to pursue our business strategy and continue as a going concern. We will need to generate significant revenues to achieve profitability, and we may never do so.

Financial Operations Overview

Revenue

During the years ended December 31, 2020 and 2019, we generated approximately$0.2 million and $0.1 million, respectively, in contract research revenues, resulting from a grant with the Cystic Fibrosis Foundation in 2020 and a feasibility study agreement entered into with Genentech in 2019. Our ability to generate product revenue, which we do not expect to occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our early-stage product candidates.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of product candidates LYPDISO, MAT2203, MAT2501 and advancement of our LNC platform delivery technology, which include:

- the cost of conducting pre-clinical work;

- the cost of acquiring, developing and manufacturing pre-clinical and human clinical trial materials;

- costs for consultants and contractors associated with Chemistry and Manufacturing Controls (CMC), pre-clinical and clinical activities and regulatory operations;

- expenses incurred under agreements with contract research organizations, or CROs, including the NIH, that conduct our pre-clinical or clinical trials; and

- employee-related expenses, including salaries and stock-based compensation expense for those employees involved in the research and development process.

The table below summarizes our direct research and development expenses for our product candidates and development platform for the years ended December 31, 2020 and 2019. Our direct research and development expenses consist principally of external costs, such as fees paid to contractors, consultants, analytical laboratories and CROs and/or the NIH, in connection with our development work. We typically use our employee and infrastructure resources for manufacturing clinical trial materials, conducting product analysis, study protocol development and overseeing outside vendors. Included in "Internal Staffing, Overhead and Other" below is the cost of laboratory space, supplies, research and development (R&D) employee costs (including stock option expenses), travel and medical education.

	Years Ended December 31, (in thousands)	
	2020	**2019**
Direct research and development expenses:		
Manufacturing process development	$ 1,421	$ 1,081
Preclinical trials	744	1,538
Clinical development	5,149	2,565
Regulatory	95	190
Internal staffing, overhead and other	6,950	5,861
Total research & development	$ 14,359	$ 11,235

Research and development activities are central to our business model. We expect our research and development expenses to increase because product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage human trials. In addition, we will look to strategically expand the use of our drug platform technology through additional development work. During 2021, we will be focused on advancing our lead product candidates, MAT2203, to efficacy data in the treatment of CM, accelerating the preclinical development of MAT2501 and also expanding application of our LNC platform delivery technology through collaborations with third parties. We have also initiated a process to identify a suitable partner to continue the development of LYPDISO following the announcement of topline date from the ENHANCE-IT study in February 2021.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive and finance functions. Other general and administrative expenses include facility costs, insurance, investor relations expenses, professional fees for legal, patent review, consulting and accounting/audit services. We anticipate that our general and administrative expenses will increase during 2021 due to the increased expenses related to employee compensation and insurance costs.

Sale of Net Operating Losses (NOLs)

Income obtained from selling unused net operating losses (NOLs) and unused research tax credits under the New Jersey Technology Business Tax Certificate Program was approximately $1.1 million and $1.0 million for the years ended December 31, 2020 and 2019, respectively.

Other Income, net

Other income, net is largely comprised of interest income (expense) and franchise taxes.

Application of Critical Accounting Policies and Accounting Estimates

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operation and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain.

For a description of our significant accounting policies, refer to "Note 3 – *Summary of Significant Accounting Policies*." Of these policies, the following are considered critical to an understanding of our Consolidated Financial Statements as they require the application of the most difficult, subjective and complex judgments; (i) Stock-based compensation, (ii) Fair value measurements, (iii) Research and development costs, (iv) Goodwill and other intangible assets, and (v) Basic and diluted net loss per common share.

Current Operating Trends

Our current R&D efforts are focused on advancing our lead LNC product candidates, MAT2203, through clinical development toward an initial indication for the treatment of CM, accelerating preclinical development of MAT2501 with the assistance of the CFF, and expanding application of our LNC platform delivery technology through collaborations with third parties. Our R&D expenses consist of manufacturing work and the cost of active pharmaceutical ingredients and excipients used in such work, fees paid to consultants for work related to clinical trial design and regulatory activities, fees paid to providers for conducting various clinical studies as well as for the analysis of the results of such studies, and for other medical research addressing the potential efficacy and safety of our drugs. We believe that significant investment in product development is a competitive necessity, and we plan to continue these investments in order to be in a position to realize the potential of our product candidates and proprietary technologies.

We expect that most of our R&D expenses in the near-term future will be incurred in support of our current and future preclinical and clinical development programs rather than technology development. These expenditures are subject to numerous uncertainties relating to timing and cost to completion. We test compounds in numerous preclinical studies for safety, toxicology and efficacy. At the appropriate time, subject to the approval of regulatory authorities, we expect to conduct early-stage clinical trials for each drug candidate. We anticipate funding these trials ourselves, and possibly with the assistance of federal grants, contracts or other agreements. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain products in order to focus our resources on more promising products. Completion of clinical trials may take several years, and the length of time generally varies substantially according to the type, complexity, novelty and intended use of a product candidate.

The commencement and completion of clinical trials for our products may be delayed by many factors, including lack of efficacy during clinical trials, unforeseen safety issues, slower than expected participant recruitment, lack of funding or government delays. In addition, we may encounter regulatory delays or rejections as a result of many factors, including results that do not support the intended safety or efficacy of our product candidates, perceived defects in the design of clinical trials and changes in regulatory policy during the period of product development. As a result of these risks and uncertainties, we are unable to accurately estimate the specific timing and costs of our clinical development programs or the timing of material cash inflows, if any, from our product candidates. Our business, financial condition and results of operations may be materially adversely affected by any delays in, or termination of, our clinical trials or a determination by the FDA that the results of our trials are inadequate to justify regulatory approval, insofar as cash in-flows from the relevant drug or program would be delayed or would not occur.

Results of Operations

Years Ended December 31, 2020 and 2019

The following table summarizes our operating expenses for the years ended December 31, 2020 and 2019 (in thousands):

	Years Ended December 31,	
	2020	**2019**
Revenues	$ 158	$ 90
Expenses:		
Research and development	$ 14,359	$ 11,235
General and administrative	10,006	7,776
Operating Expenses	$ 24,365	$ 19,011
Sale of net operating losses (NOLs)	$ 1,073	$ 1,007

Revenues. We generated approximately $158.3 thousand and approximately $89.8 thousand for the years ended December 31, 2020 and 2019, respectively. Amounts earned in 2020 consists of contract research revenue resulting from a grant with the Cystic Fibrosis Foundation and the feasibility study agreement with Genentech Inc. The amount earned in 2019 consists of contract research revenue resulting from a grant with the Cystic Fibrosis Foundation.

Research and Development expenses. R&D expense for the year ended December 31, 2020 was approximately $14.4 million, an increase of approximately $3.2 million over the prior year. R&D expenses increased mainly due to higher preclinical and clinical development expenses of approximately $1.8 million, employee compensation of approximately $1.3 million and manufacturing development and other expenses of approximately $0.1 million. We expect R&D expenses to increase during 2021 as we move our clinical development programs forward and continue to invest in our LNC platform delivery technology and our laboratory & manufacturing facility.

General and Administrative expenses. General and administrative expense for the year ended December 31, 2020 was approximately $10.0 million, an increase of approximately $2.2 million over prior year. The increase in general and administrative expense was primarily due to an increase in employee related expenses of approximately $1.7 million and professional fees of approximately $0.4 million.

Sale of net operating losses (NOLs). The Company recognized approximately $1.1 million and $1.0 million for the years ended December 31, 2020 and 2019, respectively, in connection with the sale of state net operating losses and state research and development credits to a third party under the New Jersey Technology Business Tax Certificate Program.

Liquidity and capital resources

Sources of Liquidity

We have funded our operations since inception primarily through private placements of our preferred stock and our common stock and common stock warrants. As of December 31, 2020, we have raised a total of approximately $150.9 million in gross proceeds and $138.4 million, net, from sales of our equity securities.

As of December 31, 2020, we had cash, cash equivalents and marketable securities, excluding restricted cash, totaling $58.7 million.

2020 At-The-Market Sales Agreement

On July 2, 2020, we entered into an At-The-Market Sales Agreement (the "Sales Agreement") with BTIG, LLC ("BTIG"), pursuant to which we may offer and sell, from time

to time, through BTIG, as sales agent and/or principal, shares of our common stock having an aggregate offering price of up to $50,000,000, subject to certain limitations on the amount of common stock that may be offered and sold by us set forth in the Sales Agreement. BTIG will be paid a 3% commission on the gross proceeds from each sale. We may terminate the Sales Agreement at any time; BTIG may terminate the Sales Agreement in certain limited circumstances. As of December 31, 2020, we did not sell any shares of our common stock under the ATM Sales Agreement. During January 2021, BTIG sold 3,023,147 shares of the Company's common stock generating gross proceeds of approximately $5.8 million and net proceeds of approximately $5.6 million, after deducting BTIG's commission on gross proceeds.

2020 Common Stock Offering

On January 14, 2020, the Company closed an underwritten public offering of its common stock. The offering resulted in the sale of approximately 32.3 million shares to the public at a price of $1.55 per share. The Company generated net proceeds of approximately $46.7 million. The Company granted the underwriters a 30-day option (the "option") to purchase up to approximately 4.8 million additional shares of common stock subject to the same terms and conditions. No additional shares of the Company's common stock were sold pursuant to this option.

2019 Common Stock Offering

On March 19, 2019, the Company closed an underwritten public offering of its common stock. The offering resulted in the sale of approximately 27.3 million shares to the public at a price of $1.10 per share. The Company generated net proceeds of approximately $27.8 million. The Company granted the underwriters a 30-day option (the "option") to purchase up to approximately 4.1 million additional shares of common stock subject to the same terms and conditions. If the underwriters exercise the option in full, additional net proceeds of approximately $4.2 million will be generated. On March 28, 2019, approximately 2.2 million additional shares were sold pursuant to the option at a price of $1.10 per share, resulting in net proceeds to the Company of approximately $2.3 million.

2018 Series B Preferred Stock Offering

On June 19, 2018, the Company entered into a placement agency agreement with ThinkEquity, a Division of Fordham Financial Management, Inc., as placement agent , relating to the offering, issuance and sale of up to 8,000 shares of the Company's Series B Convertible Preferred Stock, par value $0.0001 per share with a stated value of $1,000 per share which are convertible into an aggregate of up to 16,000,000 shares of the Company's common stock, par value $0.0001 per share at an initial conversion price of $0.50 per share of Common Stock and an additional up to 7,200,000 shares of Common Stock issuable upon payment of dividends under the Series B Preferred Stock . The offering closed on June 21, 2018 raising a gross amount of $8 million with a net raise of $7.1 million after deducting issuance costs.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the period set forth below (in thousands):

	Years Ended December 31	
	2020	**2019**
Cash used in operating activities	$ (17,368)	$ (14,092)
Cash used in investing activities	(40,667)	(6,011)
Cash provided by financing activities	48,047	29,852
Net (decrease)/increase in cash and cash equivalents and restricted cash	$ (9,988)	$ 9,749

Operating Activities

Net cash used in operating activities for the year ended December 31, 2020 was approximately $17.4 million, compared to approximately $14.1 million in the prior year. The increase of approximately $3.3 million for the period was primarily due to an increase in net loss, approximately $5.1 million, offset by the increase in non-cash stock-based compensation expense of approximately $1.6 million. We expect that there will be an increase in cash used in operations during 2021 due to higher research and development expenses as we continue to move our product candidates and LNC platform delivery technology forward in their development cycles.

Investing Activities

Approximately $40.7 million and approximately $6.0 million of cash was used in investing activities for the years ended December 31, 2020 and 2019, respectively. The increase of $34.7 million was primarily due to the net increase in purchases and maturities of our marketable securities of approximately $40.7 million during 2020 compared to the purchase of our marketable securities of approximately $5.6 million in December 2019 and the decrease of approximately $0.4 million in purchases of leasehold improvements and equipment.

Financing Activities

Net cash provided by financing activities was approximately $48.0 million and approximately $29.9 million for the years ended December 31, 2020 and 2019, respectively. The increase of $18.1 million in cash provided by financing activities is primarily due to the approximately $46.7 million of net proceeds from the January 2020 public offering of common stock compared to the approximately $30.1 million of net proceeds from the March 2019 public offering of common stock, as well as an increase of approximately $0.8 million from the exercising of certain warrants and approximately $0.6 million from the exercising of stock options during 2020.

Funding Requirements and Other Liquidity Matters

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if and as we:

- conduct further preclinical and clinical studies of MAT2203, our lead product candidate, even is such studies are primarily financed with non-dilutive funding from NIH;
- support the conduct of further preclinical studies of MAT2501, even if such studies are primarily financed with non-dilutive funding from the CFF;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- require the manufacture of larger quantities of product candidates for clinical development and potentially commercialization;

- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, quality control and scientific personnel; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts and personnel and infrastructure necessary to help us comply with our obligations as a public company.

We expect that our existing cash, cash equivalents and marketable securities, coupled with the approximately $5.6 million of net proceeds generated from the recently completed sales of common stock, will be sufficient to fund our operating expenses and capital expenditures requirements into 2024.

Until such time, if ever, that we can generate product revenues sufficient to achieve profitability, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, government or other third-party funding, collaborations and licensing arrangements. We do not have any committed external source of funds other than limited grant funding from the CFF and NIH. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, the ownership interest of our stockholders may be materially diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights of our common stockholders. Debt financing and preferred equity financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. Securing additional financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

Refer to Note 10 – *"Commitments"* in the accompanying notes to the consolidated financial statements for a discussion of the Company's contractual obligations and commitments.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, such as relationships with unconsolidated entities or financial partnerships, which are often referred to as structured finance or special purpose entities, established for the purpose of facilitating financing transactions that are not required to be reflected on our balance sheets.

RECENT ACCOUNTING PRONOUNCEMENTS

Refer to Note 3 - "*Significant Accounting Policies*," in the accompanying notes to the consolidated financial statements for a discussion of recent accounting pronouncements.

Item 7A. Quantitative And Qualitative Disclosures About Market Risk

Our exposure to market risk is limited to our cash, cash equivalents and marketable securities. As of December 31, 2020, we had $58.7 million in cash, cash equivalents and marketable securities. Such interest-earning instruments carry a degree of interest rate risk. The primary objectives of our investment activities are to preserve principal, provide liquidity and maximize income without significantly increasing risk. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operation. We do not have any foreign currency or other derivative financial instruments.

Item 8. Financial Statements And Supplementary Data

Our financial statements, together with the independent registered public accounting firm report thereon, are incorporated by reference from the applicable information set forth in Part IV Item 15, "Exhibits, Financial Statement Schedules" of this Annual Report on Form 10-K.

Item 9. Changes In And Disagreements With Accountants On Accounting And Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure Controls and Procedures:

As of December 31, 2020, under the supervision and with the participation of our principal executive officer and principal financial officer we have evaluated, the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2020.

Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports that we filed or submitted under the Exchange Act is recorded, processed, summarized and reported within time periods specified by 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 in our reports filed under the Exchange Act is accumulated and communicated to our management, including principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

As disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 9, 2020, management previously identified a material weakness in our internal controls over financial reporting. Based on management's evaluation, this material weakness was remediated as of December 31, 2020.

Management's Report on Internal Control over Financial Reporting:

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive officer and principal financial officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. Our control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, any projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies and procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting based on criteria established in "Internal Control—Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has concluded as of December 31, 2020, our internal control over financial reporting was effective, as management did not identify any deficiencies in internal control over financial reporting that was determined to be a material weakness.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

The previously identified material weakness during the year ended December 31, 2019 which has been remediated included not having designed and implemented a sufficient level of formal financial reporting and operating policies and procedures that define how transactions should have been initiated, processed, recorded and reported, including presentation and disclosure in the consolidated financial statements.

Management implemented its remediation plan by enhancing operational procedures related to purchasing, receiving and recording expenditures, including consulting with our third-party internal auditors throughout the period while formalizing and testing our review procedures.

Changes in Internal Control Over Financial Reporting:

There was no change, except as part of our remediation of the deficiency in internal controls described above, in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") that occurred during the period covered by this report that has materially affected or is reasonably likely to materially affect our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers And Corporate Governance

All directors hold office for one-year terms until the election and qualification of their successors. Officers are appointed by our board of directors and serve at the discretion of the board, subject to applicable employment agreements. The following table sets forth information regarding our executive officers and the members of our board of directors.

Name	Age	Position(s)
Herbert Conrad	88	Chairman of the Board, Director
Jerome D. Jabbour	46	Chief Executive Officer and President, Director
James J. Ferguson	67	Chief Medical Officer
Keith A. Kucinski	51	Chief Financial Officer
Hui Liu	53	Chief Technology Officer
Raphael J. Mannino	73	Chief Scientific Officer
Theresa Matkovits	53	Chief Development Officer
Patrick G. LePore	65	Vice Chairman of the Board, Director
Eric Ende	52	Director
Natasha Giordano	59	Director
James S. Scibetta	56	Director
Matthew Wikler	71	Director

Management

Jerome D. Jabbour, JD was appointed Chief Executive Officer in March 2018. He has served as our President since March 2016. Prior to that he served as our Executive Vice President, Chief Business Officer, General Counsel and Secretary since October 2013 and as one of our directors from April 2012 until November 2013. Mr. Jabbour is also a Co-founder of Matinas BioPharma. Prior to joining our management team, he was the Executive Vice President and General Counsel of MediMedia USA, or MediMedia, from 2012 to October 2013, a privately held diversified health care services company. Prior to MediMedia, he was the Senior Vice President, Head of Global Legal Affairs of Wockhardt Limited (2008-2012), a global pharmaceutical and biotechnology company, and Senior Counsel and Assistant Secretary at Reliant (2004-2008). Earlier in his career, he held positions as Commercial Counsel at Alpharma, Inc. (2003-2004) and as a Corporate Associate at Lowenstein Sandler LLP (1999-2003). Mr. Jabbour earned his J.D. from Seton Hall University School of Law in New Jersey and a B.A. in Psychology from Loyola University in Baltimore.

James J. Ferguson, MD was appointed Chief Medical Officer in February 2019. Prior to joining the Company he served as the Cardiovascular and Bone Therapeutic Area Head for U.S. Medical Affairs, at Amgen (NASDAQ: AMGN), a multinational biopharmaceutical company. Prior to Amgen Dr. Ferguson held a number of senior positions at AstraZeneca, a multinational pharmaceutical and biopharmaceutical company, including Vice President of US Cardiovascular Medical and Scientific External Relations, Therapeutic Area Vice President of Cardiovascular Global Medical Affairs, U.S. Development Brand Leader for BRILINTA ®, and Senior Director, Clinical Research. Before joining AstraZeneca he was Vice President of Surgical and Critical Care for The Medicines Company. In addition, Dr. Ferguson had more than 20 years of academic experience as the Associate Director of Clinical Cardiology Research at the Texas Heart Institute, Co-Director of the Cardiology Fellowship Training Program at St. Luke's Episcopal Hospital in Houston, where he was an Associate Professor of Medicine at Baylor College of Medicine, and a Clinical Assistant Professor at the University of Texas Health Science Center at Houston. Dr. Ferguson has served on the Editorial Board of numerous peer-reviewed journals and has over 400 publications and book chapters. Dr. Ferguson received his B.A. (cum Laude) in Biology from Harvard University, his M.D. from the University of Pennsylvania School of Medicine and completed his post-graduate training

at the University of Michigan Medical Center, Ann Arbor, Michigan and Beth Israel Hospital, Boston, Massachusetts.

Keith A. Kucinski, MBA, CPA was appointed Chief Financial Officer in January 2019. He most recently served as Chief Financial Officer at RemedyOne, a privately held healthcare consulting organization. Prior to that, he served as Vice President & Treasurer at Par Pharmaceutical Companies, Inc., an operating company of Endo International plc, a leading generics and specialty-branded pharmaceutical company. In addition, Mr. Kucinski held various roles at Barr Pharmaceuticals, Inc., including Senior Director, Finance & Corporate Development and Assistant Treasurer & Senior Director, Finance. Mr. Kucinski is a Certified Public Accountant. He received his Bachelor of Business Administration in Accounting from the University of Notre Dame and an M.B.A. in Finance & Management from the Leonard N. Stern School of Business at New York University.

Theresa Matkovits, PhD has served as Chief Development officer since October 2018. She joined the Company after having most recently served as the Chief Operating Officer of ContraVir Pharmaceuticals (NASDAQ: CTRV) (now Hepion Pharmaceuticals), a clinical stage biopharmaceutical company. From 2013 to 2015, Dr. Matkovits served as Global Program Leader at NPS Pharmaceuticals, a specialty pharmaceutical company that was purchased by Shire in 2015. Prior to her time at NPS, Dr. Matkovits was Vice President, Innovation Leader at The Medicines Company. Earlier in her career, Dr. Matkovits held a number of global leadership positions at Novartis across Global Development and the U.S. Commercial Organization, including as Head, Strategic Planning and Operations, U.S. Medical and Drug Regulatory Affairs. Dr. Matkovits began her career at the Roche Institute of Molecular Biology and Organon where she held positions in clinical development in women's health and research in the area of infertility. Dr. Matkovits serves on the Board of Directors of BioSurplus and also serves as an Independent Director of Appili Therapeutics (TSX: APLIF).Dr. Matkovits was selected to participate in Women in Bio's Boardroom Ready Program in 2016. Dr. Matkovits earned her Ph.D. in Biochemistry and Molecular Biology from the University of Medicine and Dentistry of NJ.

Hui Liu, PhD, MBA was appointed Chief Technology Officer in December 2020. Dr. Liu has over two decades of experience in the formulation of small molecules, biologics, and gene therapies. He joined the Company from Seqirus, a global leader in influenza vaccine development and pandemic preparedness, where he served as the Director of Formulation and Delivery from 2017 to 2020. Prior to his time at Seqirus, Dr. Liu was the CMC Director at Cellics Therapeutics, a privately held biotechnology company based in San Diego. His early career focused on ophthalmic drug development at two leading eye care companies, Alcon and Allergan plc. At Alcon, he led multiple CMC teams as the Senior Technical Lead from 2015 to 2017. During his time at Allergan, Dr. Liu played a critical role in realizing a paradigm shift for standard glaucoma care, focusing on sustained delivery drug development in his role as a Principal Scientist. Previously, he worked on pigment nanoparticle encapsulation at Hewlett-Packard. Dr. Liu holds a Ph.D. in Polymer Chemistry from the University of Michigan, an M.B.A. from the University of Massachusetts Amherst, and a B.S. from the University of Science and Technology of China.

Raphael J. Mannino has served as our Chief Scientific Officer since September 2015. From 1990 until August 2015, Dr. Mannino was an Associate Professor of Pathology and Laboratory Medicine at Rutgers University, New Jersey Medical School. Dr. Mannino founded BioDelivery Sciences, Inc., and served as its President, Chief Executive Officer and Chief Scientific Officer and a member of its Board of Directors from 1995 to 2000, when it was acquired by BioDelivery Sciences International, Inc. (NASDAQ: BDSI). Dr. Mannino served as BDSI's Executive Vice President and Chief Scientific Officer from 2001 to 2009 and a member of its Board of Directors from 2000 to 2007. Dr. Mannino's previous experience includes positions as Assistant, then Associate Professor, Albany Medical College (1980 to 1990), and Instructor then Assistant Professor, Rutgers Medical School (1977 to 1980). His postdoctoral training was from 1973 to 1976 at the Biocenter in Basel, Switzerland. Dr. Mannino received his Ph.D. in Biological Chemistry in 1973 from the Johns Hopkins University, School of Medicine.

Directors

Herbert Conrad has served as our Chairman of the Board since July 2013 and as Chairman of the Board of Matinas BioPharma, Inc. since October 2012. He also serves on the board of directors of Celldex Therapeutics, Inc. (NASDAQ: CLDX), biopharmaceutical company focused on the development and commercialization of immunotherapies and other targeted biologics, and as an Advisor to the Seaver Autism Center at Mount Sinai Hospital. Mr. Conrad was the President of the U.S. Pharmaceuticals Division of Hoffmann-La Roche, Inc. from 1982 until his retirement in 1993. Prior to that, he held many positions of increasing responsibility at Roche Pharmaceuticals in the United States. Mr. Conrad previously served on the board of directors of Arbutus Biopharma Corporation (NASDAQ: ABUS), Pharmasset, Inc. (chairman), Savient Pharmaceuticals, Inc. (NASDAQ: SVNT), Dura Pharmaceuticals, Inc., UroCor, Inc., GenVec, Inc. (NASDAQ: GNVC) (chairman), Sicor, Inc., Bone Care International, Inc. (chairman), Sapphire Therapeutics, Inc. (chairman), the medical advisory board of Henry Schein Inc. (NASDAQ: HSIC), and he was a Director and Co-Founder of Reliant Pharmaceuticals. Pharmasset was acquired by Gilead Sciences, Inc. for $11 billion in 2011 and Reliant was acquired by GlaxoSmithKline for $1.65 billion in 2007. He received B.S. and M.S. degrees from the Brooklyn College of Pharmacy and an honorary Doctorate in Humane Letters from Long Island University. We believe Mr. Conrad is qualified to serve on our board of directors due to his extensive expertise and experience in the life sciences industry and his extensive board experience.

Patrick LePore has served as our Vice Chairman of the Board since September 5, 2018. Mr. LePore served as chairman, chief executive officer and president of Par Pharmaceuticals, Inc. (NYSE:PRX), an operating company of Endo International plc, a generics and specialty branded pharmaceutical company, from September 2006 until the company's acquisition by private equity investor TPG in November 2012. He remained as chairman of the new company where he led the sale of the company to Endo Pharmaceuticals (NASDAQ: ENDP). Mr. LePore began his career with Hoffmann LaRoche. Later, he founded Boron LePore and Associates, a medical communications company, which he took public in 1997 and which was eventually sold to Cardinal Health. He is chairman of the board of directors of Lannett Company, Inc. (NYSE: LCI), a pharmaceutical company, and is a trustee of Villanova University. He previously served as a member of the board of directors of PharMerica Corporation (NYSE: PMC) and Innoviva, Inc. (NASDAQ: INVA). Mr. LePore earned his bachelor's degree from Villanova University and Master of Business Administration from Fairleigh Dickinson University. We believe Mr. LePore is qualified to serve on our board of directors due to his executive leadership and significant experience in the life sciences industry and his public company board experience.

Jerome D. Jabbour. See description under "Management."

Eric Ende has served on our board of directors since April 2017. Dr. Ende is president of Ende BioMedical Consulting Group, a privately-held consulting company which is focused on helping life sciences companies raise capital, identify licensing partners, and optimize corporate structure as well as analyzing both private and public investment opportunities for clients within the life sciences industry, a position he has held since 2009. Dr. Ende serves as co-founder, chief executive and chief financial officer of WellFit Holdings, LLC, a private company focused on developing fitness technologies. In addition, Dr. Ende consulted with Icahn Enterprises in their efforts to appoint board members at Forest Labs, Genzyme, Biogen IDEC, and Amylin. Dr. Ende served on the board of directors and as a member of the audit and risk management committee of Genzyme Corp. (NASDAQ: GENZ) from 2010 until it was acquired by Sanofi (NSYE: SNY) in 2011. Dr. Ende is currently serving on the Technology Transfer Committee of Mount Sinai Innovation Partners and served as the Chairman of the Unsecured Creditor's Committee overseeing the bankruptcy of Egenix, Inc. From 2002 through 2008, Dr. Ende was the senior biotechnology analyst at Merrill Lynch. From 2000 through 2002, Dr. Ende was the senior biotechnology analyst at Banc of America Securities and, from 1997 to 2000, he was a biotechnology analyst at Lehman Brothers. Dr. Ende received an MBA in Finance & Accounting from NYU – Stern Business School in 1997, an MD from Mount Sinai School of Medicine in 1994, and a BS in Biology and Psychology from Emory University in 1990. We believe Dr. Ende is qualified to serve on our board of directors due to his industry experience, including as president of Ende BioMedical Consulting Group and as a biotechnology analyst, and his prior public company board experience.

Natasha Giordano. Ms. Giordano has served as a member of our board of directors since September 2020. Ms. Giordano has been President, Chief Executive Officer and director of PLx Pharma Inc. (NASDAQ: PLXP) since January 2016. Previously, Ms. Giordano served as the Interim Chief Executive Officer of ClearPoint Learning, Inc., a privately held learning and training platform company, from May 2015 through November 2015. She also served on the ClearPoint board of directors from December 2009

through November 2015. Previously, Ms. Giordano served as the Chief Executive Officer of Healthcare Corporation of America (NYSE: HCA), a leading healthcare provider, from January 2014 through August 2014. From June 2009 to August 2012, Ms. Giordano served as Chief Operating Officer and then as Chief Executive Officer, President and a member of the board of directors of Xanodyne Pharmaceuticals, Inc., a privately-held a branded specialty pharmaceutical company with development and commercial capabilities focused on pain management and women's health. Prior to that, she served as President, Americas, for Cegedim Dendrite (formerly Dendrite International Inc.), a global technology services company, from 2007 to 2008 and as Senior Vice President of the Global Customer Business Unit of Cegedim Dendrite from 2004 to 2007. Ms. Giordano holds a Bachelor of Science degree in nursing from Wagner College. We believe Ms. Giordano is qualified to serve as a director due to her extensive experience in commercialization, general management and knowledge of the pharmaceutical and health care industries.

James S. Scibetta has served as a member of our board of directors since November 2013. He is currently Chief Executive Officer of Maverick Therapeutics, a development stage immune-oncology company. Prior to Maverick, he was President and Chief Financial Officer of Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX), a specialty pharmaceutical company, a position he has held since October 2015. Prior to that, Mr. Scibetta was the Chief Financial Officer of Pacira since 2008. Prior to joining Pacira in August 2008, he served as a consultant to Genzyme Corporation following the sale of Bioenvision Inc. (NASDAQ: BIVN) to Genzyme in 2007. From 2006 to 2007 Mr. Scibetta was CFO of Bioenvision. From 2001 to 2006, he was Executive Vice President and Chief Financial Officer of Merrimack Pharmaceuticals Inc. (NASDAQ: MACK). Mr. Scibetta has previously served on the board of directors at the following life sciences companies: Nephros Inc. (NASDAQ: NEPH), Merrimack Pharmaceuticals and Labopharm Inc. Prior to his executive management experience, Mr. Scibetta spent over a decade in investment banking where he was responsible for sourcing and executing transactions for a broad base of public and private healthcare and life sciences companies. Mr. Scibetta received his Bachelor of Science in Physics from Wake Forest University and an MBA from the University of Michigan. We believe Mr. Scibetta is qualified to serve on our board of directors because of his extensive management experience in the pharmaceutical industry, his investment banking experience and his experience as a chief financial officer and audit committee member of several publicly traded companies.

Matthew Wikler has served as a member of our board of directors since January 2018. Dr. Wikler currently serves as the Principal of Infectious Disease Technology Development Consulting (IDTD Consulting), a privately-held consulting firm, where he provides clinical, medical and regulatory strategic insight to companies developing new technologies for the treatment and prevention of infectious diseases, a position he has held since 2015. Prior to that from 2012 to 2015, Dr. Wikler served at The Medicines Company (NASDAQ: MDCO), a biopharmaceutical company, as VP, New Business Ventures and VP and Medical Director, Infectious Disease Care. Over the course of his career Dr. Wikler held senior leaderships positions for a number of pharmaceutical companies, including as Chief Development Officer of Rib-X Pharmaceuticals, Inc., a privately-held biopharmaceutical company developing new antibiotics to provide superior coverage, safety and convenience for the treatment of serious and life-threatening infections, President and Chief Executive Officer of IASO Pharma Inc., a privately-held clinical stage biotechnology company focused on the development of antibacterial and antifungal therapeutics, the Institute for One World Health, a 501(c)(3) nonprofit drug development organization, Mpex Pharmaceuticals, Inc., a privately-held company focused on developing and manufacturing therapies for antibiotic resistance with focus on gram-negative organisms, Peninsula Pharmaceuticals, Inc., a privately held biopharmaceutical company focused on developing and commercializing antibiotics to treat life-threatening infections (acquired by Johnson & Johnson (NYSE: JNJ)), ViroPharma Incorporated (NASDAQ: VPHM), Bristol-Myers Squibb Company (NYSE:BMY), and Ortho-McNeil Pharmaceutical (a division of Johnson & Johnson). Dr. Wikler began his career at Smith Kline & French/Smith Kline Beecham where he held positions of increasing responsibilities over ten years. Dr. Wikler held a variety of positions at the FDA, including the Deputy Director of the Division of Anti-Infective Drug Products. Dr. Wikler earned a B.A. in Chemistry from Franklin and Marshall, an M.D. degree from Temple University School of Medicine, and his M.B.A. from the University of Pennsylvania Wharton School of Business. He completed his Infectious Diseases Fellowship at the Hospital of the University of Pennsylvania and is a Fellow of the Infectious Diseases Society of America. We believe Dr. Wikler is qualified to serve on our board of directors because of his extensive management experience in the pharmaceutical industry and his clinical and regulatory experience in the area of infectious diseases.

There are no family relationships among any of our directors or executive officers.

Scientific Advisory Board

We believe in seeking and attracting scientific and clinical leaders in the field of cardiovascular medicine as well as infectious diseases to provide counsel and support our growth. We have established two separate Scientific Advisory Board which consist of individuals who are experts in their chosen fields and recipients of many academic honors and awards.

Board Committees

Our board of directors has four standing committees — an Audit Committee, a Compensation Committee, a Nominating and Corporate Governance Committee and a Scientific Advisory Committee.

Audit Committee. The Audit Committee oversees and monitors our financial reporting process and internal control system, reviews and evaluates the audit performed by our registered independent public accountants and reports to the Board any substantive issues found during the audit. The Audit Committee is directly responsible for the appointment, compensation and oversight of the work of our registered independent public accountants. The Audit Committee reviews and approves all transactions with affiliated parties. James Scibetta, Herbert Conrad, Eric Ende and Natasha Giordano currently serve as members of the Audit Committee, with James Scibetta, serving as its chairman. All members of the Audit Committee have been determined to be financially literate and are considered independent directors as defined under The NYSE American's listing standards and applicable SEC rules and regulations. Mr. Scibetta qualifies as an audit committee "financial expert" as that term is defined by SEC regulations. The Audit Committee met four times during 2020. Our Board has adopted an Audit Committee Charter, which is available for viewing at *www.matinasbiopharma.com*.

Compensation Committee. The Compensation Committee provides advice and makes recommendations to the Board in the areas of employee salaries, benefit programs and director compensation. The Compensation Committee also reviews the compensation of our executive officers, including our chief executive officer, and makes recommendations in that regard to the Board as a whole. Eric Ende, Patrick LePore, James Scibetta and Matthew Wikler currently serve as members of the Compensation Committee, with Eric Ende serving as its chairman. All members of the Compensation Committee are considered independent directors as defined under The NYSE American's listing standards. The Compensation Committee met three times during 2020. Our Board has adopted a Compensation Committee Charter, which is available for viewing at *www.matinasbiopharma.com*.

Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee nominates individuals to be elected to the full Board by our stockholders. The Nominating and Corporate Governance Committee considers recommendations from stockholders if submitted in a timely manner in accordance with the procedures set forth in our Bylaws and applies the same criteria to all persons being considered. Herbert Conrad, Eric Ende, Patrick LePore and James Scibetta currently serve as members of the Nominating and Corporate Governance Committee, with Herbert Conrad serving as its chairman. All members of the Nominating and Corporate Governance Committee are considered independent directors as defined under The NYSE American's listing standards. The Nominating and Corporate Governance Committee met three times during 2020. Our Board has adopted a Nominating and Corporate Governance Charter, which is available for viewing at *www.matinasbiopharma.com*.

Scientific Advisory Committee. The Board of Directors has established a Scientific Advisory Committee consisting of Dr. Matthew Wikler, Chair, and Jerome D. Jabbour. The primary function of the Scientific Advisory Committee is to assist the Board in undertaking periodic reviews of our research and development efforts, and clinical trials, and reporting to the Board about developments and strategy, at such times as the Committee determines to be appropriate.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial and accounting officer, or persons performing similar functions. A copy of the code is posted on the corporate governance section of our website, which is located at www.matinasbiopharma.com. If we make any substantive amendments to, or grant waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website.

Delinquent Section 16(a) Reports

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and executive officers, and persons who are beneficial owners of more than 10% of a registered class of our equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission (the "SEC"). These persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations that no other reports were required during the fiscal year ended December 31, 2020, all reports required to be filed under Section 16(a) were filed on a timely basis.

Item 11. Executive Compensation

Summary Compensation Table – 2020

The following table presents information regarding the total compensation awarded to, earned by, or paid to our chief executive officer and the two most highly-compensated executive officers who were serving as executive officers as of December 31, 2020 for services rendered in all capacities to us for the years ended December 31, 2020 and December 31, 2019. These individuals are our named executive officers for 2020.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($) [1]	All Other Compensation ($)	Total ($)
Jerome D. Jabbour	2020	500,000	250,000	2,180,085	-	2,930,085
Chief Executive Officer	2019	444,792	200,000	680,384	-	1,325,176
James J. Ferguson	2020	410,000	150,000	1,090,043		1,650,043
Chief Medical Officer	2019	319,444	50,000	319,926	62,945[2]	752,315
Theresa Matkovits	2020	367,500	122,500	763,030	-	1,253,030
Chief Development Officer	2019	350,000	30,625	317,513	-	698,138

[1] Amounts reflect the grant date fair value of option awards granted in 2020 and 2019 in accordance with Accounting Standards Codification Topic 718. These amounts do not correspond to the actual value that will be recognized by the named executive officers.

[2] Mr. Ferguson was reimbursed for relocation costs.

Narrative Disclosure to Summary Compensation Table

Employment Agreements with Our Named Executive Officers

Jabbour

On March 22, 2018, we entered into an employment agreement with Mr. Jabbour. Under the terms of Mr. Jabbour's employment agreement, Mr. Jabbour received a signing bonus of $84,000 and a base salary of $350,000 per year. In addition, Mr. Jabbour is eligible to receive an annual bonus, which is targeted at 50% of his base salary but which may be adjusted by our Compensation Committee based on his individual performance and our performance as a whole. Mr. Jabbour is also eligible to receive option grants at the discretion of our Compensation Committee. Mr. Jabbour received an option grant to purchase 1,000,000 shares on March 22, 2018 and is also eligible to receive additional option grants and equity grants at the discretion of our Compensation Committee. If we terminate Mr. Jabbour's employment without cause or Mr. Jabbour resigns with good reason (absent a change of control), we are required to pay him severance of up to twelve months of his base salary plus COBRA benefits for twelve months. In addition, the vesting of 50% of his outstanding options will be accelerated in full upon such termination and Mr. Jabbour will be provided with an extension through two years after the separation date of the exercise period for his vested stock options. If we terminate Mr. Jabbour's employment without cause during the 24-month period immediately following a change of control or Mr. Jabbour resigns with good reason during the 24-month period immediately following a change of control, we are required to pay him severance of up to 24 months of his base salary and his target annual bonus plus 18 months of COBRA benefits. In addition, his outstanding options will be vested in full and Mr. Jabbour will be provided with an extension through two years after the separation date of the exercise period for his vested stock options. Mr. Jabbour is also subject to a customary non-disclosure agreement, pursuant to which Mr. Jabbour has agreed to be subject to a non-compete during the term of his employment and for a period of eighteen months following termination of his employment.

Ferguson

On February 22, 2019, we entered into an employment agreement with Mr. Ferguson which was effective as of February 25, 2019. Under the terms of Mr. Ferguson's employment agreement, Mr. Ferguson receives a base salary of $375,000 per year. In addition, Mr. Ferguson is eligible to receive an annual bonus, which is targeted at 35% of his base salary but which may be adjusted by our Compensation Committee based on his individual performance and our performance as a whole. Mr. Ferguson is also eligible to receive option grants at the discretion of our Compensation Committee. If we terminate Mr. Ferguson's employment without cause or Mr. Ferguson resigns with good reason, we are required to pay him severance of up to twelve months of his base salary plus benefits. In addition, the vesting of 50% of his outstanding options will be accelerated in full upon such termination. Mr. Ferguson is also subject to a customary non-disclosure agreement, pursuant to which Mr. Ferguson has agreed to be subject to a non-compete during the term of his employment and for a period of eighteen months following termination of his employment.

Matkovits

On September 25, 2018, we entered into an employment agreement with Ms. Matkovits which was effective as of October 15, 2018. Under the terms of Ms. Matkovits' employment agreement, Ms. Matkovits receives a base salary of $350,000 per year. In addition, Ms. Matkovits is eligible to receive an annual bonus, which is targeted at 35% of her base salary but which may be adjusted by our Compensation Committee based on her individual performance and our performance as a whole. Ms. Matkovits is also eligible to receive option grants at the discretion of our Compensation Committee. If we terminate Ms. Matkovits' employment without cause or Ms. Matkovits resigns with good reason, we are required to pay her severance of up to twelve months of his base salary plus benefits. In addition, the vesting of 50% of her outstanding options will be accelerated in full upon such termination. Ms. Matkovits is also subject to a customary non-disclosure agreement, pursuant to which Ms. Matkovits has agreed to be subject to a non-compete during the term of her employment and for a period of eighteen months following termination of his employment.

Outstanding Equity Awards at Fiscal Year-End Table – 2020

The following table summarizes, for each of the named executive officers, the number of shares of common stock underlying outstanding stock options held as of December 31, 2020.

	Option Awards			
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date
Jerome D. Jabbour	-	500,000	$ 0.82	Jun 16, 2030
	-	1,000,000	$ 2.27	Dec 31, 2029
	343,750	406,250	$ 1.08	Feb 10, 2029
	687,500	312,500	$ 0.98	Mar 21, 2028
	400,000	-	$ 3.32	Feb 20, 2027
	350,000	-	$ 0.43	Feb 4, 2026
	175,000	-	$ 0.41	Jan 27, 2025
	350,000	-	$ 1.28	July 20, 2024
	350,000	-	$ 0.94	Oct 3, 2023
James J. Ferguson	-	250,000	$ 0.82	Jun 16, 2030
	-	500,000	$ 2.27	Dec 31, 2029
	160,417	189,583	$ 1.09	Feb 24, 2029
Theresa Matkovits	-	175,000	$ 0.82	Jun 16, 2030
	-	350,000	$ 2.27	Dec 31, 2029
	160,417	189,583	$ 1.08	Feb 10, 2029
	189,584	160,416	$ 0.79	Oct 14, 2028

2013 Equity Compensation Plan

General

On August 2, 2013, our Board of Directors adopted the 2013 Equity Compensation Plan pursuant to the terms described herein. The 2013 Equity Compensation Plan was approved by the stockholders on August 7, 2013. Effective May 8, 2014, upon the approval of our Board of Directors and our stockholders, we amended and restated our 2013 Equity Compensation Plan, primarily to include "evergreen" provisions, which state provide that number of shares of common stock available for issuance under the Plan is subject to an automatic annual increase on January 1 of each year beginning in 2015 equal to 4% of the number of shares of common stock outstanding on December 31 of the preceding calendar year or a lesser number of shares of common stock determined by the Board of Directors; to amend the definition of "fair market value"; and to increase the limits on awards under the Plan. The 2013 Equity Compensation Plan, as amended and restated, is referred to herein as the "2013 Plan."

The general purpose of the 2013 Plan is to provide an incentive to our employees, directors, consultants and advisors by enabling them to share in the future growth of our business. Our Board of Directors believes that the granting of stock options, restricted stock awards, unrestricted stock awards and similar kinds of equity-based compensation promotes continuity of management and increases incentive and personal interest in the welfare of our Company by those who are primarily responsible for shaping and carrying out our long range plans and securing our growth and financial success.

Our Board of Directors believes that the 2013 Plan will advance our interests by enhancing our ability to (a) attract and retain employees, consultants, directors and advisors who are in a position to make significant contributions to our success; (b) reward our employees, consultants, directors and advisors for these contributions; and (c) encourage employees, consultants, directors and advisors to take into account our long-term interests through ownership of our shares.

Description of the 2013 Equity Compensation Plan

The following description of the principal terms of the 2013 Plan is a summary and is qualified in its entirety by the full text of the 2013 Plan, which is attached as Exhibit 10.1 hereto.

***Administration*.** The 2013 Plan will be administered by the Compensation Committee of our Board of Directors, provided that the entire Board of Directors may act in lieu of the Compensation Committee on any matter, subject to certain requirements set forth in the 2013 Plan. The Compensation Committee may grant options to purchase shares of our common stock, stock appreciation rights, stock units, restricted shares of our common stock, performance shares, performance units, incentive bonus awards, other cash-based awards and other stock-based awards. The Compensation Committee also has broad authority to determine the terms and conditions of each option or other kind of award, and adopt, amend and rescind rules and regulations for the administration of the 2013 Plan. Subject to applicable law, the Compensation Committee may authorize one or more reporting persons (as defined in the 2013 Plan) or other officers to make awards (other than awards to reporting persons, or other officers whom the Compensation Committee has specifically authorized to make awards). No awards may be granted under the 2013 Plan on or after the ten year anniversary of the adoption of the 2013 Plan by our Board of Directors, but awards granted prior to such tenth anniversary may extend beyond that date.

***Eligibility*.** Awards may be granted under the 2013 Plan to any person who is an employee, officer, director, consultant, advisor or other individual service provider of the Company or any subsidiary, or any person who is determined by the Compensation Committee to be a prospective employee, officer, director, consultant, advisor or other individual service provider of the Company or any subsidiary.

Shares Subject to the 2013 Plan. As of March 14, 2021 the aggregate number of shares of common stock available for issuance in connection with awards granted under the 2013 Plan is 36,952,460 shares, subject to customary adjustments for stock splits, stock dividends or similar transactions (the "Initial Limit"). Incentive Stock Options may be granted under the 2013 Plan with respect to all of those shares. The number of shares of common stock available for issuance under the 2013 Plan will automatically increase on January 1st of each year for a period of ten years, commencing on January 1, 2015, in an amount equal to four percent (4%) of the total number of shares of common stock outstanding on December 31st of the preceding calendar year (the "Annual Increase"). Notwithstanding the foregoing, the Board of Directors may act prior to the first day of any calendar year, to provide that there shall be no increase in the share reserve for such calendar year or that the Annual Increase in the share reserve for such calendar year shall be a lesser number of shares of common stock than would otherwise occur pursuant to the preceding sentence. The number of shares of common stock which may be

issued in respect of Incentive Stock Options is equal to the Current Limit, and will be increased on each January 1, by the Annual Increase for such calendar year.

To the extent that any award under the 2013 Plan payable in shares of common stock is forfeited, cancelled, returned to the Company for failure to satisfy vesting requirements or upon the occurrence of other forfeiture events, or otherwise terminates without payment being made thereunder, the shares of common stock covered thereby will be available for future grants under the 2013 Plan. Shares of common stock that otherwise would have been issued upon the exercise of a stock option or in payment with respect to any other form of award, that are surrendered in payment or partial payment of taxes required to be withheld with respect to the exercise of such stock option or the making of such payment, will also be available for future grants under the 2013 Plan.

Terms and Conditions of Options. Options granted under the 2013 Plan may be either "incentive stock options" that are intended to meet the requirements of Section 422 of the Internal Revenue Code of 1986, as amended (the "Code") or "nonqualified stock options" that do not meet the requirements of Section 422 of the Code. The Compensation Committee will determine the exercise price of options granted under the 2013 Plan. The exercise price of stock options may not be less than the fair market value, on the date of grant, per share of our common stock issuable upon exercise of the option (or 110% of fair market value in the case of incentive options granted to a ten-percent stockholder).

If on the date of grant the common stock is listed on a stock exchange or national market system, the fair market value shall generally be the closing sale price as of such date, or if there were no trades recorded on such date, then the most recent date preceding such date on which trades were recorded. If on the date of grant the common stock is traded in an over-the-counter market, the fair market will generally be the average of the closing bid and asked prices for the shares of common stock as of such date, or, if there are no closing bid and asked prices for the shares of common stock on such date, then the average of the bid and asked prices for the shares of common stock on the most recent date preceding such date on which such closing bid and asked prices are available. If the common stock is not listed on a national securities exchange or national market system or traded in an over-the-counter market, the fair market value shall be determined by the Compensation Committee in a manner consistent with Section 409A of the Internal Revenue Code of 1986, as amended. Notwithstanding the foregoing, if on the date of grant the common stock is listed on a stock exchange or is quoted on a national market system, or is traded in an over-the-counter market, then solely for purposes of determining the exercise price of any grant of a stock option or the base price of any grant of a stock appreciation right, the Compensation Committee may, in its discretion, base fair market value on the last sale before or the first sale after the grant, the closing price on the trading day before or the trading day of the grant, the arithmetic mean of the high and low prices on the trading day before or the trading day of the grant, or any other reasonable method using actual transactions of the common stock as reported by the exchange or market on which the common stock is traded. In addition, the determination of fair market value also may be made using any other method permitted under Treasury Regulation section 1.409A-1(b)(5)(iv).

No option may be exercisable for more than ten years from the date of grant (five years in the case of an incentive stock option granted to a ten-percent stockholder). Options granted under the 2013 Plan will be exercisable at such time or times as the Compensation Committee prescribes at the time of grant. No employee may receive incentive stock options that first become exercisable in any calendar year in an amount exceeding $100,000. The Compensation Committee may, in its discretion, permit a holder of a nonqualified stock option to exercise the option before it has otherwise become exercisable, in which case the shares of our common stock issued to the recipient will continue to be subject to the vesting requirements that applied to the option before exercise.

Generally, the option price may be paid in cash or by bank check, or such other means as the Compensation Committee may accept. As set forth in an award agreement or otherwise determined by the Compensation Committee, in its sole discretion, at or after grant, payment in full or part of the exercise price of an option may be made (a) in the form of shares of common stock that have been held by the participant for such period as the Compensation Committee may deem appropriate for accounting purposes or otherwise, valued at the fair market value of such shares on the date of exercise; (ii) by surrendering to the Company shares of common stock otherwise receivable on exercise of the option; (iii) by a cashless exercise program implemented by the Compensation Committee in connection with the 2013 Plan; and/or (iv) by such other method as may be approved by the Compensation Committee and set forth in an award agreement.

No option may be transferred other than by will or by the laws of descent and distribution, and during a recipient's lifetime an option may be exercised only by the recipient or the recipient's guardian or legal representative. However, the Compensation Committee may permit the transfer of a nonqualified stock option, share-settled stock appreciation right, restricted stock award, performance share or share-settled other stock-based award either (a) by instrument to the participant's immediate family (as defined in the 2013 Plan), (b) by instrument to an inter vivos or testamentary trust (or other entity) in which the award is to be passed to the participant's designated beneficiaries, or (c) by gift to charitable institutions. The Compensation Committee will determine the extent to which a holder of a stock option may exercise the option following termination of service.

Stock Appreciation Rights. The Compensation Committee may grant stock appreciation rights independent of or in connection with an option. The Compensation Committee will determine the terms applicable to stock appreciation rights. The base price of a stock appreciation right will be determined by the Compensation Committee, but will not be less than 100% of the fair market value of a share of our common stock with respect to the date of grant of such stock appreciation right. The maximum term of any SAR granted under the 2013 Plan is ten years from the date of grant. Generally, each SAR stock appreciation right will entitle a participant upon exercise to an amount equal to:

- the excess of the fair market value of a share of common stock on the date of exercise of the stock appreciation right over the base price of such stock appreciation right, multiplied by
- the number of shares as to which such stock appreciation right is exercised.

Payment may be made in shares of our common stock, in cash, or partly in common stock and partly in cash, all as determined by the Compensation Committee.

Restricted Stock and Stock Units. The Compensation Committee may award restricted common stock and/or stock units under the 2013 Plan. Restricted stock awards consist of shares of stock that are transferred to a participant subject to restrictions that may result in forfeiture if specified conditions are not satisfied. Stock units confer the right to receive shares of our common stock, cash, or a combination of shares and cash, at a future date upon or following the attainment of certain conditions specified by the Compensation Committee. The Compensation Committee will determine the restrictions and conditions applicable to each award of restricted stock or stock units, which may include performance-based conditions. Dividends with respect to restricted stock may be paid to the holder of the shares as and when dividends are paid to stockholders or at the times of vesting or other payment of the restricted stock award. Stock unit awards may be granted with dividend equivalent rights, which may be accumulated and may be deemed reinvested in additional stock units, as determined by the Compensation Committee in its discretion. If any dividend equivalents are paid while a stock unit award is subject to restrictions, the dividend equivalents shall be subject to the same restrictions on transferability as the underlying stock units, unless otherwise set forth in an award agreement. Unless the Compensation Committee determines otherwise, holders of restricted stock will have the right to vote the shares.

Performance Shares and Performance Units. The Compensation Committee may award performance shares and/or performance units under the 2013 Plan. Performance shares and performance units are awards which are earned during a specified performance period subject to the attainment of performance criteria, as established by the Compensation Committee. The Compensation Committee will determine the restrictions and conditions applicable to each award of performance shares and performance units.

Incentive Bonus Awards. The Compensation Committee may award Incentive Bonus Awards under the 2013 Plan. Incentive Bonus Awards may be based upon the attainment of specified levels of Company or subsidiary performance as measured by pre-established, objective performance criteria determined at the discretion of the Compensation Committee. Incentive Bonus Awards will be paid in cash or common stock, as set forth in an award agreement

Other Stock-Based and Cash-Based Awards. The Compensation Committee may award other types of equity-based or cash-based awards under the 2013 Plan, including the grant or offer for sale of unrestricted shares of our common stock and payment in cash or otherwise of amounts based on the value of shares of common stock.

Effect of Certain Corporate Transactions. The Compensation Committee may, at the time of the grant of an award, provide for the effect of a change in control (as defined in the 2013 Plan) on any award, including (i) accelerating or extending the time periods for exercising, vesting in, or realizing gain from any award, (ii) eliminating or modifying the performance or other conditions of an award, (iii) providing for the cash settlement of an award for an equivalent cash value, as determined by the Compensation Committee, or (iv) such other modification or adjustment to an award as the Compensation Committee deems appropriate to maintain and protect the rights and interests of participants upon or following a change in control. The Compensation Committee may, in its discretion and without the need for the consent of any recipient of an award, also take one or more of the following actions contingent upon the occurrence of a change in control: (a) cause any or all outstanding options and stock appreciation rights to become immediately exercisable, in whole or in part; (b) cause any other awards to become non-forfeitable, in whole or in part; (c) cancel any option or stock appreciation right in exchange for a substitute option; (d) cancel any award of restricted stock, stock units, performance shares or performance units in exchange for a similar award of the capital stock of any successor corporation; (e) redeem any restricted stock, stock unit, performance share or performance unit for cash and/or other substitute consideration with a value equal to the fair market value of an unrestricted share of our common stock on the date of the change in control; (f) cancel any option or stock appreciation right in exchange for cash and/or other substitute consideration based on the value of our common stock on the date of the change in control , and cancel any option or stock appreciation right without any payment if its exercise price exceeds the value of our common stock on the date of the change in control; (g) cancel any stock unit or performance unit held by a participant affected by the change in control in exchange for cash and/or other substitute consideration with a value equal to the fair market value per share of common stock on the date of the change in control, or (h) make such other modifications, adjustments or amendments to outstanding awards as the Compensation Committee deems necessary or appropriate.

Amendment, Termination. The Compensation Committee may amend the terms of awards in any manner not inconsistent with the 2013 Plan, provided that no amendment shall adversely affect the rights of a participant with respect to an outstanding award without the participant's consent. In addition, our board of directors may at any time amend, suspend, or terminate the 2013 Plan, provided that (i) no such amendment, suspension or termination shall materially and adversely affect the rights of any participant under any outstanding award without the consent of such participant and (ii) to the extent necessary and desirable to comply with any applicable law, regulation, or stock exchange rule, the 2013 Plan requires us to obtain stockholder consent. Stockholder approval is required for any plan amendment that increases the number of shares of common stock available for issuance under the 2013 Plan or changes the persons or classes of persons eligible to receive awards.

Tax Withholding

The Company has the power and right to deduct or withhold, or require a participant to remit to the Company, the minimum statutory amount to satisfy federal, state, and local taxes, domestic or foreign, required by law or regulations to be withheld.

Director Compensation

In October 2013, we adopted a compensation policy pursuant to which our non-employee directors receive annualized compensation of $20,000 per year, with an additional $10,000 per year for the Chairman of the Board and the Chair of the Audit Committee, as well as an additional $5,000 per year for the Chairs of the Compensation and Nomination & Governance Committees. In addition, our independent board members will receive an option grant of 150,000 options, with the exception of the Chairman of the Board, who will be granted 200,000 options. In August 2014, we revised our compensation policy to provide that directors will receive restricted stock in lieu of cash fees.

In January 2018, we adopted an amended compensation policy for our non-employee directors. The amended policy provides for the following compensation amounts payable in cash, or upon election by such non-employee director, in shares of unrestricted common stock: (i) each non-employee director, other than the chairman of the board is entitled to receive an annual fee of $50,000, (ii) the chairman of the board is entitled to receive an additional annual fee of $25,000, (iii) the chair of our audit committee is entitled to receive an annual fee from us of $15,000 and other members of our audit committee are entitled to receive $7,500; (iv) the chair of our compensation committee is entitled to receive an annual fee from us of $10,000 and other members of our compensation committee are entitled to receive $6,000; and (v) the chair of our nominating and corporate governance committee is entitled to receive an annual fee from us of $7,500 and other members are entitled to receive $4,000. In addition, In September 2018, our Board approved an additional annual fee of $20,000 for our vice chair.

As of the date of each annual meeting of the shareholders, each non-employee director will receive an option grant to purchase shares of our common stock valued at $80,000 as determined by the Black Scholes method on the date of grant under our existing equity incentive plan, or any other equity incentive plan we may adopt in the future, which shall vest in twelve equal monthly installments.

All fees under the director compensation policy are paid on a quarterly basis in arrears and no per meeting fees are paid. All fees may be paid in unrestricted shares of common stock at the election of the director. We also reimburse non-employee directors for reasonable expenses incurred in connection with attending board of director and committee meetings.

Director Compensation Table – 2020

The following table summarizes the annual compensation for our non-employee directors during 2020.

Name	Cash Compensation ($)	Stock Awards ($) (1)	Option Awards ($) (1)	Total ($)
Herbert Conrad	90,000	-	80,000	170,000
Eric Ende	71,500	-	80,000	151,500
Natasha Giordano	17,344	-	160,000	177,344
Patrick G. LePore	80,000	-	80,000	160,000
James S. Scibetta	75,000	-	80,000	155,000
Adam Stern	41,984	-	-	41,984
Matthew Wikler	-	63,500	80,000	143,500

(1) Amounts reflect the grant date fair value of stock awards and option awards granted in 2020 in accordance with Accounting Standards Codification Topic 718. These amounts do not correspond to the actual value that will be recognized by the directors.

Compensation Committee Interlocks and Insider Participation

The Compensation Committee of the Board of Directors is currently, and was for the last fiscal year, composed of the following four non-employee directors: Eric Ende, Chair, Patrick G. LePore, James Scibetta and Matthew Wikler. No member of the Compensation Committee is or was formerly an officer or an employee of the Company during the last fiscal year. In addition, no executive officer of the Company serves on the compensation committee or board of directors of a company for which any of the Company's directors serve as an executive officer. Please see Item 13.

Item 12. Security Ownership Of Certain Beneficial Owners And Management And Related Stockholder Matters.

The following table sets forth the number of shares of common stock beneficially owned as of March 14, 2021 by:

- each of our stockholders who is known by us to beneficially own 5% or more of our common stock;
- each of our executive officers;
- each of our directors; and
- all of our directors and current executive officers as a group.

Beneficial ownership is determined based on the rules and regulations of the SEC. A person has beneficial ownership of shares if such individual has the power to vote and/or dispose of shares. This power may be sole or shared and direct or indirect. Applicable percentage ownership in the following table is based on 204,276,412 shares outstanding as of March 14, 2021. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock that are subject to options or warrants held by that person and exercisable as of, or within 60 days of, March 14, 2021 are counted as outstanding. These shares, however, are not counted as outstanding for the purposes of computing the percentage ownership of any other person(s). Except as may be indicated in the footnotes to this table and pursuant to applicable community property laws, each person named in the table has sole voting and dispositive power with respect to the shares of common stock set forth opposite that person's name. Unless indicated below, the address of each individual listed below is c/o Matinas BioPharma Holdings, Inc., 1545 Route 206 South, Suite 302, Bedminster, NJ 07921.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
5% Stockholders		
Boxer Capital, LLC (1)	11,478,634	5.6%
Directors and Executive Officers		
Jerome D. Jabbour (2)	3,159,567	1.5%
Herbert Conrad (3)	5,753,293	2.8%
Eric Ende (4)	974,686	*%
Natasha Giordano (5)	63,982	*%
Patrick LePore (6)	844,666	*%
James Scibetta (7)	1,543,052	*%
Matthew Wikler (8)	916,697	*%
James J. Ferguson (9)	439,601	*%
Keith A. Kucinski (10)	570,034	*%
Hui Liu (11)	-	*%
Raphael Mannino (12)	2,231,444	1.1%
Theresa Matkovits (13)	590,637	*%
Directors and Executive Officers as a group (12 persons) (14)	17,087,659	8.0%

* Less than 1%

(1) Based solely on information contained in a Schedule 13G/A filed on February 16, 2021. Shared voting and dispositive power of the shares is held by Boxer Capital, LLC, Boxer Asset Management Inc. and Joe Lewis. The address for each reporting person is 11682 El Camino Real, Suite 320, San Diego, CA 92130.

(2) Includes (i) 15 convertible preferred shares if converted to 30,000 common shares, and (ii) 2,705,243shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 14, 2021. Does not include 2,657,257 shares of common stock underlying options that are not exercisable within sixty days of March 14, 2021.

(3) Includes (i) 100 convertible preferred shares if converted to 200,000 common shares, and (ii) 1,098,727 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 14, 2021. Does not include 51,085 shares of common stock underlying options that are not exercisable within sixty days of March 14, 2021.

(4) Includes (i) 12 convertible preferred shares if converted to 24,000 common shares, and (ii) 835,394 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 14, 2021. Does not include 51,085 shares of common stock underlying options that are not exercisable within sixty days of March 14, 2021.

(5) Includes 63,982 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 14, 2021. Does not include 223,935 shares of common stock underlying options that are not exercisable within sixty days of March 14, 2021.

(6) Includes 444,666 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 14, 2021. Does not include 63,584 shares of common stock underlying options that are not exercisable within sixty days of March 14, 2021.

(7) Includes (i) 12 convertible preferred shares if converted to 24,000 common shares, and (ii) 897,894 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 14, 2021. Does not include 51,085 shares of common stock underlying options that are not exercisable within sixty days of March 14, 2021.

(8) Includes (i) 6 convertible preferred shares if converted to 12,000 common shares, and (ii) 660,394 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 14, 2021. Does not include 76,085 shares of common stock underlying options that are not exercisable within sixty days of March 14, 2021.

(9) Includes 439,601 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 14, 2021. Does not include 985,399 shares of common stock underlying options that are not exercisable within sixty days of March 14, 2021.

(10) Includes 475,534 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 14, 2021. Does not include 899,466 shares of common stock underlying options that are not exercisable within sixty days of March 14, 2021.

(11) Does not include 600,000 shares of common stock underlying options that are not exercisable within sixty days of March 14, 2021.

(12) Includes (i) 10 convertible preferred shares if converted to 20,000 common shares, and (ii) 781,879 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 14, 2021. Does not include 353,121 shares of common stock underlying options that are not exercisable within sixty days of March 14, 2021.

(13) Includes 590,637 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 14, 2021. Does not include 884,363 shares of common stock underlying options that are not exercisable within sixty days of March 14, 2021.

(14) See notes (2) through (13).

Securities Authorized for Issuance under Equity Compensation Plans

The following table summarizes information about our equity compensation plans as of December 31, 2020.

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options (a)	Weighted-Average Exercise Price of Outstanding Options (b)	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)(2)
Equity compensation plans approved by stockholders(1)	22,550,715	$ 1.26	3,020,284
Equity compensation plans not approved by stockholders	—	—	—
Total	22,550,715	$ 1.26	3,020,284

(1) The amounts shown in this row include securities under the Matinas BioPharma Holdings, Inc. Amended and Restated 2013 Equity Incentive Plan (the "2013 Plan").

(2) In accordance with the "evergreen" provision in our 2013 Plan, an additional 8,004,537 shares were automatically made available for issuance on the first trading day of 2021, which represents 4% of the number of shares outstanding on December 31, 2020; these shares are excluded from this calculation.

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

Certain Relationships and Related Party Transactions

Other than compensation arrangements for our named executive officers and directors, there has been no transaction or series of similar transactions, since January 1, 2020, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed the lesser of (i) $120,000 and (ii) one percent of the average of our total assets at year-end for the last two completed fiscal years; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Indemnification Agreements

We entered into indemnification agreements with our directors and executive officers. The indemnification agreements provide for indemnification against expenses, judgments, fines and penalties actually and reasonably incurred by an indemnitee in connection with threatened, pending or completed actions, suits or other proceedings, subject to certain limitations. The indemnification agreements also provide for the advancement of expenses in connection with a proceeding prior to a final, non-appealable judgment or other adjudication, provided that the indemnitee provides an undertaking to repay to us any amounts advanced if the indemnitee is ultimately found not to be entitled to indemnification by us. The indemnification agreement set forth procedures for making and responding to a request for indemnification or advancement of expenses, as well as dispute resolution procedures that apply to any dispute between us and an indemnitee arising under the Indemnification Agreements.

Policies and Procedures for Related Party Transactions

We have adopted a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock, any members of the immediate family of any of the foregoing persons and any firms, corporations or other entities in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person has a 5% or greater beneficial ownership interest, which we refer to collectively as related parties, are not permitted to enter into a transaction with us without the prior consent of our board of directors acting through the audit committee or, in certain circumstances, the chairman of the audit committee. Any request for us to enter into a transaction with a related party, in which the amount involved exceeds $100,000 and such related party would have a direct or indirect interest must first be presented to our audit committee, or in certain circumstances the chairman of our audit committee, for review, consideration and approval. In approving or rejecting any such proposal, our audit committee, or the chairman of our audit committee, is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances, the extent of the benefits to us, the availability of other sources of comparable products or services and the extent of the related party's interest in the transaction.

Director Independence

Based on information requested from and provided by each of our directors, our board of directors has determined that Messrs. Herbert Conrad, Eric Ende, Patrick LePore, James Scibetta, Matthew Wikler and Ms. Natasha Giordano are "independent directors" as such term is defined in the rules of The NYSE American's corporate governance requirements and Rule 10A-3 promulgated under the Securities Exchange Act of 1934, as amended.

Item 14. Principal Accounting Fees And Services

The following table represents aggregate fees billed to the Company for the fiscal years ended December 31, 2020 and 2019, by EisnerAmper LLP, the Company's independent registered public accounting firm.

	Years Ended December 31,	
	2020	2019

	(in thousands)	
Audit Fees	$ 297	$ 370
Tax Fees	-	-
Total Fees	$ 297	$ 370

Audit Fees consist of fees billed for professional services rendered for the audit of our annual financial statements, audit of internal controls over financial reporting, review of our interim consolidated financial statements and comfort letters.

Tax Fees are for tax-related services related primarily to tax consulting and tax planning.

The Audit Committee pre-approves all auditing services and any non-audit services that the independent registered public accounting firm is permitted to render under Section 10A (h) of the Exchange Act. The Audit Committee may delegate the pre-approval to one of its members, provided that if such delegation is made, the full Audit Committee must be presented at its next regularly scheduled meeting with any pre-approval decision made by that member.

Part IV

Item 15. Exhibits And Financial Statement Schedules

Exhibit No.	Description
2.1	Merger Agreement, dated July 11, 2013, by and among the Company, Matinas Merger Sub, Inc., and Matinas BioPharma, Inc. (incorporated by reference to Exhibit 2.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
2.2	Agreement and Plan of Merger (the "Merger Agreement") with Aquarius Biotechnologies, Inc., a Delaware corporation ("Aquarius"), Saffron Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Company ("Merger Sub") and J. Carl Craft, as the stockholder representative (incorporated herein by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on January 30, 2015).
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
3.2	Bylaws (incorporated by reference to Exhibit 3.2 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
3.3	Certificate of Amendment, dated October 29, 2015 to Certificate of Incorporation. (incorporated herein by reference to the Company's Current Report on Form 8-K filed with the SEC on November 5, 2015).
3.4	Certificate of Designation of Series A Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed August 1, 2016 with the Securities and Exchange Commission).
3.5	Certificate of Designation of Series B Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed June 19, 2018 with the Securities and Exchange Commission).
4.1	Common Stock Specimen (incorporated by reference to Exhibit 4.1 of the Company's Annual Report on Form 10-K for the year ended December 31, 2016, filed March 31, 2017 with the Securities and Exchange Commission).
4.2	Form of Warrant (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
4.3	Form of 2015 Investor Warrant. (incorporated by reference to Exhibit 4.4 to the post-effective amendment No. 1 to Form S-1 filed with the SEC on April 17, 2015).
4.4	Form of 2015 Placement Agent Warrant. (incorporated by reference to Exhibit 4.5 to the post-effective amendment No. 1 to Form S-1 filed with the SEC on April 17, 2015).
4.5	Form of 2016 Placement Agent Warrant (incorporated by reference to Exhibit 4.7 to the Registration Statement on Form S-1 filed with the SEC on November 2, 2016).
4.6	Description of Securities*
10.1	Matinas BioPharma Holdings, Inc. Amended and Restated 2013 Equity Compensation Plan (incorporated herein by reference to Exhibit 10.6 to the Company's Annual Report on Form 10-K filed on March 31, 2015.) †
10.2	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.7 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014). †

10.3	Form of Non-Qualified Stock Option Agreement (incorporated by reference to Exhibit 10.8 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014). †
10.5	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.14 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014). †
10.6	Lease, effective as of November 4, 2013, by and between the company and A-K Bedminster Associates, L.P. (incorporated by reference to Exhibit 10.17 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
10.7	Amended and Restated Exclusive License Agreement dated as of January 29, 2015, by and between Rutgers, the State University of New Jersey and Aquarius Biotechnologies, Inc. (incorporated herein by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K filed on March 31, 2015). +
10.9	Lease Agreement, dated as of December 15, 2016, by and between CIP II/AR Bridgewater Holdings LLC, and Matinas BioPharma Holdings, Inc. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on April 28, 2017).
10.10	Therapeutic Development Award Agreement, dated November 19, 2020, between Matinas BioPharma Holdings, Inc. and the Cystic Fibrosis Foundation.*
10.11	At-The-Market Sales Agreement, dated July 2, 2020, between Matinas BioPharma Holdings, Inc. and BTIG, LLC (incorporated herein by reference to Exhibit 1.01 to the Company's Current Report on Form 8-K filed with the SEC on July 2, 2020).
21.1	Subsidiaries Index*
23.1	Consent of EisnerAmper LLP*
31.1	Certification of President and Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
31.2	Certification of Acting Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1	Section 1350 Certifications**
101	The following financial information from the Annual Report on Form 10-K for the fiscal year ended December 31, 2020, formatted in XBRL (eXtensible Business Reporting Language), is filed electronically herewith: (i) Consolidated Balance Sheets as of December 31, 2020 and 2019; (ii) Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2020 and 2019; (iii) Consolidated Statement of Changes in Stockholders' Equity (Deficit) for the Years Ended December 31, 2020 and 2019; (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2020 and 2019; and (v) Notes to Consolidated Financial Statements.*

+ Confidential treatment has been requested for certain provisions of this Exhibit pursuant to Rule 24b-2 promulgated under the Securities Exchange Act of 1934, as amended.

† Indicates a management contract or compensation plan, contract or arrangement.
* Filed herewith.
** Furnished herewith.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Bedminster, State of New Jersey on March 29, 2021.

MATINAS BIOPHARMA HOLDINGS, INC.

By: */s/ Jerome D. Jabbour*
Name: Jerome D. Jabbour
Title: Chief Executive Officer

By: */s/ Keith A. Kucinski*
Name: Keith A. Kucinski
Title: Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Person	Capacity	Date
/s/ Jerome D. Jabbour Jerome D. Jabbour	Chief Executive Officer and Director (Principal Executive Officer)	March 29, 2021
/s/ Keith A. Kucinski Keith A. Kucinski	Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2021
/s/ Herbert Conrad Herbert Conrad	Chairman of the Board	March 29, 2021
/s/ Patrick G. LePore Patrick G. Lepore	Vice Chairman of the Board	March 29, 2021
/s/ Eric Ende Eric Ende	Director	March 29, 2021
/s/ Matthew A. Wikler Matthew A. Wikler	Director	March 29, 2010
/s/ James S. Scibetta James S. Scibetta	Director	March 29, 2021
/s/ Natasha Giordano Natacha Giordano	Director	March 29, 2021

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Matinas BioPharma Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Matinas BioPharma Holdings, Inc. and Subsidiaries as of December 31, 2020 and 2019, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2020 and 2019, and the consolidated results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

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

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

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accruals for research and development expenses

As disclosed in the consolidated statements of operations, for the year ended December 31, 2020, the Company incurred significant research and development ("R&D") expenses, which amounted to approximately $14.4 million. At December 31, 2020, the Company had accrued $1.4 million for R&D expenses on the consolidated balance sheet. A large amount of the Company's R&D expenses are service fees paid to contract research organizations ("CROs). The R&D activities with these CROs are documented in contractual agreements and are typically performed over an extended period, and there may be several milestones of the services in one agreement. Therefore, the allocation of the service expenses based on the progress of the R&D projects and the milestones completed for the appropriate financial reporting period involved judgement and estimation.

We identified management's estimate of accruals for R&D expenses as a critical audit matter due to the significance of these expenses to the financial statements and the subjectivity involved in estimating the progress of the R&D projects and service fees accrued for the completion of milestones by the CROs. As a result, auditor judgement and additional testing were required to perform procedures and evaluate audit evidence related to the accruals for R&D expenses.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. Our audit procedures related to the accruals for R&D expenses included the following, among others, (i) we obtained an understanding of management's process and evaluated the design of controls related to the accrual process for R&D expenses; (ii) we read selected research agreements to evaluate whether the progress and the completion of milestones reported by the representatives of the CROs and the corresponding service fees are based on the respective contractual terms, (iii) we sent confirmations to CROs, on a sample basis, to confirm the amount of the total R&D service fees incurred for the year and the amounts of outstanding payables under the terms of the contracts, and (iv) we selected projects from the open contract list at year end and made inquiries of the Company research personnel regarding the project status, and we also inspected invoices received subsequent to year-end and additional documents and correspondence with the CROs, supporting management's estimate of R&D expenditures.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2011.

EISNERAMPER LLP
Iselin, New Jersey
March 29, 2021

Matinas BioPharma Holdings, Inc.
Consolidated Balance Sheets

	December 31,	
	2020	**2019**
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 12,432,481	$ 22,170,438
Marketable securities	46,246,573	5,604,634
Restricted cash	136,000	250,000
Prepaid expenses and other current assets	2,739,791	1,897,784
Total current assets	61,554,845	29,922,856
Non-current assets:		
Leasehold improvements and equipment - net	1,523,950	1,749,259
Operating lease right-of-use assets - net	3,276,639	3,761,207
Finance lease right-of-use assets - net	58,007	116,968
In-process research and development	3,017,377	3,017,377
Goodwill	1,336,488	1,336,488
Restricted cash - security deposits	200,000	336,000
Total non-current assets	9,412,461	10,317,299
Total assets	$ 70,967,306	$ 40,240,155
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 349,941	$ 679,310
Accrued expenses and other liabilities	2,795,329	1,939,510
Operating lease liabilities - current	391,498	423,741
Financing lease liabilities - current	30,853	54,673
Total current liabilities	3,567,621	3,097,234
Non-current liabilities:		
Deferred tax liability	341,265	341,265
Operating lease liabilities - net of current portion	3,304,063	3,695,561
Financing lease liabilities - net of current portion	23,660	54,513

Total non-current liabilities	3,668,988	4,091,339
Total liabilities	7,236,609	7,188,573
Stockholders' equity:		
Series B Convertible preferred stock, stated value $1,000 per share, 8,000 shares authorized as of December 31, 2020 and 2019, respectively; 4,361 and 4,577 shares issued and outstanding as of December 31, 2020 and 2019, respectively; (liquidation preference - $4,361,000 at December 31, 2020)	3,797,705	3,985,805
Common stock par value $0.0001 per share, 500,000,000 shares authorized at December 31, 2020 and 2019, respectively; 200,113,431 and 163,156,984 issued and outstanding as of December 31, 2020 and 2019, respectively	20,010	16,315
Additional paid-in capital	167,192,003	113,427,897
Accumulated deficit	(107,507,193)	(84,377,555)
Accumulated other comprehensive income/(loss)	228,172	(880)
Total stockholders' equity	63,730,697	33,051,582
Total liabilities and stockholders' equity	$ 70,967,306	$ 40,240,155

The accompanying notes are an integral part of these consolidated financial statements.

Matinas BioPharma Holdings, Inc.
Consolidated Statements of Operations and Comprehensive Loss

	For the Year Ended December 31,	
	2020	**2019**
Revenue:		
Contract research revenue	$ 158,333	$ 89,812
Costs and Expenses:		
Research and development	14,358,918	11,234,548
General and administrative	10,005,967	7,776,300
Total costs and expenses	24,364,885	19,010,848
Loss from operations	(24,206,552)	(18,921,036)
Sale of New Jersey net operating loss	1,073,289	1,007,082
Other income, net	686,425	541,303
Net loss	$ (22,446,838)	$ (17,372,651)
Preferred stock series A accumulated dividends	-	(338,613)
Preferred stock series B accumulated dividends	(793,442)	(585,547)
Net loss attributable to common shareholders	$ (23,240,280)	$ (18,296,811)
Net loss attributable to common shareholders per share - basic and diluted	$ (0.12)	$ (0.13)
Weighted average common shares outstanding:		
Basic and diluted	196,894,628	145,195,196
Other comprehensive income/(loss), net of tax		
Net unrealized gain/(loss) on securities available-for-sale	237,537	(880)
Reclassification of realized gain on securities available-for-sale to net loss	(8,485)	-
Other comprehensive income/(loss), net of tax	229,052	(880)
Comprehensive loss attributable to shareholders	$ (22,217,786)	$ (17,373,531)

The accompanying notes are an integral part of these consolidated financial statements.

Matinas BioPharma Holdings, Inc.
Consolidated Statements of Changes in Stockholders' Equity

	Redeemable Convertible Preferred Stock A		Redeemable Convertible Preferred Stock B		Common Stock		Additional Paid - in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	Total Stockholders' Equity
	Shares	**Amount**	**Shares**	**Amount**	**Shares**	**Amount**				
Balance, December 31, 2018	1,467,858	$ 5,583,686	4,819	$4,196,547	113,287,670	$ 11,329	$ 72,294,921	$ (65,944,759)	$ -	$ 16,141,724
Stock-based compensation	-	-	-	-	-	-	2,625,197	-	-	2,625,197
Issuance of common stock as compensation for services	-	-	-	-	441,005	44	360,462	-	-	360,506
Issuance of common stock in exchange for preferred shares A	(1,467,858)	(5,583,686)	-	-	14,678,580	1,468	5,582,218	-	-	-
Issuance of common stock in exchange for preferred shares B	-	-	(242)	(210,742)	484,000	48	210,694	-	-	-

Issuance of common stock in public offering, net of stock issuance costs ($2,315,878)	-	-	-	-	29,471,986	2,947	30,100,359	-	-	30,103,306
Issuance of common stock in exchange for Options	-	-	-	-	72,500	7	30,168	-	-	30,175
Issuance of common stock in exchange for Warrants	-	-	-	-	252,383	25	(10,105)	-	-	(10,080)
Stock dividends	-	-	-	-	4,468,860	447	2,233,983	(1,060,145)	-	1,174,285
Other comprehensive loss	-	-	-	-	-	-	-		(880)	(880)
Net loss	-	-	-	-	-	-	-	(17,372,651)	-	(17,372,651)
Balance, December 31, 2019	-	$ -	4,577	$3,985,805	163,156,984	$ 16,315	$113,427,897	$ (84,377,555)	$ (880)	$ 33,051,582
Stock-based compensation	-	-	-	-	-	-	4,184,141	-	-	4,184,141
Issuance of common stock as compensation for services	-	-	-	-	379,385	38	390,604	-	-	390,642
Issuance of common stock in exchange for preferred shares B	-	-	(216)	(188,100)	432,000	43	188,057	-	-	-
Issuance of common stock in public offering, net of stock issuance costs ($3,298,790)	-	-	-	-	32,260,000	3,226	46,700,984	-	-	46,704,210
Issuance of common stock in exchange for Options	-	-	-	-	782,073	79	820,248	-	-	820,327
Issuance of common stock in exchange for Warrants	-	-	-	-	1,737,389	172	797,409	-	-	797,581
Stock dividends	-	-	-	-	1,365,600	137	682,663	(682,800)	-	-
Other comprehensive income	-	-	-	-	-	-	-	-	229,052	229,052
Net loss	-	-	-	-	-	-	-	(22,446,838)	-	(22,446,838)
Balance, December 31, 2020	-	$ -	4,361	$3,797,705	200,113,431	$ 20,010	$167,192,003	$(107,507,193)	$ 228,172	$ 63,730,697

The accompanying notes are an integral part of these consolidated financial statements.

Matinas BioPharma Holdings, Inc.
Consolidated Statements of Cash Flows

	For the Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (22,446,838)	$ (17,372,651)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	231,058	205,964
Stock-based compensation expense	4,564,787	2,985,278
Loss on disposal of equipment	-	6,417
Amortization of operating lease right-of-use assets	484,568	452,054
Amortization of finance lease right-of-use assets	58,961	122,798
Amortization of bond discount	239,831	140
Realized gain on sale of marketable securities	8,485	-
Changes in operating assets and liabilities:		
Operating lease liabilities	(423,741)	(359,570)
Prepaid expenses and other current assets	(611,397)	(1,358,713)
Accounts payable	(329,369)	383,657
Accrued expenses and other liabilities	855,819	842,560
Net cash used in operating activities	(17,367,836)	(14,092,066)
Cash flows from investing activities:		
Purchases of marketable securities	(72,106,359)	(5,605,654)
Proceeds from sales of marketable securities	31,445,156	-
Purchases of leasehold improvements and equipment	(5,749)	(405,604)
Net cash used in investing activities	(40,666,952)	(6,011,258)
Cash flows from financing activities:		
Net proceeds from public offering of common stock	46,704,210	30,103,306
Proceeds from exercise of warrants	797,581	-
Proceeds from exercise of options	599,713	30,175
Payments of capital lease liability - principal	(54,673)	(81,715)

Payments of note payable	-	(199,842)
Net cash provided by financing activities	48,046,831	29,851,924
Net (decrease)/increase in cash, cash equivalents and restricted cash	(9,987,957)	9,748,600
Cash, cash equivalents and restricted cash at beginning of period	22,756,438	13,007,838
Cash, cash equivalents and restricted cash at end of period	$ 12,768,481	$ 22,756,438
Supplemental non-cash financing and investing activities:		
Unrealized gain (loss) on marketable securities	$ 229,052	$ (880)
Cashless exercise of warrants	$ -	$ 10,080
Stock dividends issued	$ 682,800	$ 2,234,429
Non-Cash prepaid from exercise of options	$ 220,614	$ -
Preferred stock conversion into common stock - series B	$ 188,100	$ 210,742
Unearned restricted stock grants	$ 68,521	$ 58,525
Stock dividends accrual	$ -	$ 1,174,285
Right-of-use assets obtained in exchange for liabilities	$ -	$ 4,453,028
Preferred stock conversion into common stock - series A	$ -	$ 5,583,686

The accompanying notes are an integral part of these consolidated financial statements.

Note 1 – Description of Business

Matinas BioPharma Holdings Inc. ("Holdings") is a Delaware corporation formed in 2013. Holdings is the parent company of Matinas BioPharma, Inc. ("BioPharma"), and Matinas BioPharma Nanotechnologies, Inc. ("Nanotechnologies," formerly known as Aquarius Biotechnologies, Inc.), its operating subsidiaries ("Nanotechnologies", and together with "Holdings" and "BioPharma", "the Company" or "we" or "our" or "us"). The Company is a clinical-stage biopharmaceutical company with a focus on identifying and developing novel pharmaceutical products.

Note 2 – Liquidity and Plan of Operations

The Company has experienced net losses and negative cash flows from operations each period since its inception. Through December 31, 2020, the Company had an accumulated deficit of approximately $107.5 million. The Company's net loss for the years ended December 31, 2020 and 2019 were approximately $22.4 million and $17.4 million, respectively.

The Company has been engaged in developing LYPDISO (formerly MAT-9001), its lead product candidate, as well as its lipid nanocrystal ("LNC") platform delivery technology and a pipeline of associated product candidates since 2011. To date, the Company has not obtained regulatory approval for any of its product candidates nor generated any revenue from product sales and the Company expects to incur significant expenses to complete development of its product candidates. The Company may never be able to obtain regulatory approval for the marketing of any of its product candidates in any indication in the United States or internationally and there can be no assurance that the Company will generate revenues or ever achieve profitability.

Assuming the Company obtains Food and Drug Administration ("FDA") approval for one or more of its product candidates, the Company expects that its expenses will continue to increase once the Company reaches commercial launch. The Company also expects that its research and development expenses will continue to increase as it moves forward with additional clinical studies for its current product candidates and development of additional product candidates. As a result, the Company expects to continue to incur substantial losses for the foreseeable future, and that these losses will be increasing.

To continue to fund operations, on March 19, 2019, the Company completed an underwritten public offering of common stock, generating gross cash proceeds of $30.0 million and net proceeds of approximately $27.8 million. On March 28, 2019, additional shares were sold pursuant to an over-allotment option granted to the underwriters of the public offering, resulting in additional net proceeds to the Company of approximately $2.3 million. In addition, on January 14, 2020, the Company completed an underwritten public offering of common stock, generating gross cash proceeds of approximately $50.0 million and net proceeds of approximately $46.7 million. (See Note 12 – Stockholders' Equity).

As of December 31, 2020, the Company had cash and cash equivalents of approximately $12.4 million, marketable securities of approximately $46.2 million and restricted cash of approximately $0.3 million. During January 2021, the Company sold 3,023,147 shares of common stock under its At-The-Market Sales Agreement with BTIG, LLC, generating gross proceeds of approximately $5.8 million and net proceeds of approximately $5.6 million. The Company believes the cash and cash equivalents and marketable securities on hand are sufficient to fund planned operations into 2024.

Note 3 – Summary of Significant Accounting Policies

Basis of presentation and principles of consolidation

The accompanying audited consolidated financial statements include the consolidated accounts of Holdings and its wholly owned subsidiaries, BioPharma, and Nanotechnologies. The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and reflect the operations of the Company and its wholly owned subsidiaries. All intercompany transactions have been eliminated in consolidation.

COVID-19

In March 2020, the World Health Organization declared COVID-19 a global pandemic. This contagious disease outbreak, which has continued to spread, and any related adverse public health developments, has adversely affected workforces, economics, and financial markets globally, potentially leading to an economic downturn.

The Company has been actively monitoring the COVID-19 pandemic and its impact globally. The financial results for the year ended December 31, 2020 were not significantly impacted by COVID-19. However, the Company cannot predict the impact of the progression of the COVID-19 pandemic on future results or the Company's ability to raise capital due to a variety of factors, including but not limited to the continued good health of Company employees, the ability of suppliers to continue to operate and deliver, the ability of the Company to maintain operations, any further government and/or public actions taken in response to the pandemic and ultimately the length of the pandemic.

Use of estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Significant items subject to such estimates and assumptions include, but are not limited to, the assessment of the impairment of goodwill and intangible assets, level 3 fair value measurement of financial instruments, income tax valuations, the determination of stock-based compensation, contingent consideration and research and development expenses.

Segment and geographic information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating and reporting segment.

Cash, cash equivalents and restricted cash

The Company considers all highly liquid financial instruments with original maturities of three months or less when purchased to be cash and cash equivalents and all investments with maturities of greater than three months from date of purchase are classified as marketable securities. Cash and cash equivalents consisted of cash in bank checking and savings accounts, money market funds and short-term U.S. treasury bonds that mature within three months of settlement date. The Company presents restricted cash with cash and cash equivalents in the Consolidated Statements of Cash Flows. Restricted cash represents funds the Company is required to set aside to cover building operating leases and other purposes. For a complete disclosure of the Company's cash, cash equivalents and restricted cash, see Note 4 – Cash, Cash Equivalents, Restricted Cash and Marketable Securities.

Marketable Securities

Marketable securities, all of which are available-for-sale, consist of U.S. treasury bonds and corporate debt securities. Marketable securities are carried at fair value, with unrealized gains and losses reported as accumulated other comprehensive income/(loss), except for losses from impairments which are determined to be other-than-temporary. Realized gains and losses and declines in value judged to be other-than-temporary are included in the determination of net loss and are included in other income, net. Fair values are based on quoted market prices at the reporting date. Interest and dividends on available-for-sale securities are included in other income, net. For a complete disclosure of the Company's marketable securities, see Note 4 – Cash, Cash Equivalents, Restricted Cash and Marketable Securities.

Concentration of credit risk

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash, cash equivalents, restricted cash and marketable securities. Our investment policy is to invest only in institutions that meet high credit quality standards and establishes limits on the amount and time to maturity of investments with any individual counterparty. Balances are maintained at U.S. financial institutions and are insured by the Federal Deposit Insurance Corporation ("FDIC") up to regulatory limits. The Company has not experienced any credit losses associated with its balances in such accounts.

Leasehold improvements and equipment

Equipment and leasehold improvements are stated at cost less accumulated depreciation and amortization. Depreciation on equipment is computed using the straight-line method over the estimated useful lives of the assets, which range from three to ten years. Capitalized costs associated with leasehold improvements are amortized on a straight-line basis over the lesser of the estimated useful life of the asset or the remaining term of the lease.

Goodwill and other intangible assets

Goodwill is recorded when consideration paid for an acquired entity exceeds the fair value of the net assets acquired. Goodwill is not amortized but rather is assessed for impairment at least annually on a reporting unit basis, or more frequently when events and circumstances indicate the goodwill may be impaired. U.S. GAAP provides that we have the option to perform a qualitative assessment to determine whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount. If we determine this is the case, we perform further analysis to identify and measure the amount of goodwill impairment loss to be recognized, if any.

A reporting unit is an operating segment, or one level below an operating segment. Historically, we conducted our business in a single operating segment and reporting unit. For the years ended December 31, 2020 and 2019, the Company assessed goodwill impairment by performing a qualitative test for its reporting unit. As part of the qualitative review, the Company considered its cash position and its ability to obtain additional financing in the near term to meet its operational and strategic goals and substantiate the value of its business. Based on the results of the Company's assessment, it was determined that it is more-likely-than-not that the fair value of the reporting unit is greater than its carrying amount. There were no impairments of goodwill during the years ended December 31, 2020 and 2019. If a nonrecurring fair value measurement for a goodwill impairment was required, sufficient information will be provided to permit reconciliation of the fair value of the asset categorized within the fair value hierarchy as level 3 to the amounts presented in the statement of financial position.

Indefinite lived intangible assets are composed of in-process research and development ("IPR&D") and represent projects acquired in a business combination that have not reached technological feasibility or that lack regulatory approval at the time of acquisition. These IPR&D assets are reviewed for impairment annually, or sooner if events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable, and upon establishment of technological feasibility or regulatory approval. An impairment loss, if any, is calculated by comparing the fair value of the asset to its carrying value. If the asset's carrying value exceeds its fair value, an impairment loss is recorded for the difference and its carrying value is reduced accordingly. Similar to the impairment test for goodwill, the Company may perform a qualitative approach for testing indefinite-lived intangible assets for impairment. The Company used the qualitative approach and concluded that it was more-likely-than-not that its indefinite-lived assets were not impaired during the years ended December 31, 2020 and 2019.

Leases

In February 2016, the Financial Accounting Standards Board (the "FASB") established Accounting Standards Codification ("ASC") Topic 842, "Leases", by issuing Accounting Standards Update ("ASU") No. 2016-02, which requires lessees to now recognize operating leases on the balance sheet and disclose key information about leasing arrangements. ASC Topic 842 was subsequently amended by ASU No. 2018-01, *Land Easement Practical Expedient for Transition to Topic 842; ASU No. 2018-10, Codification Improvements to Topic 842, Leases; and ASU No. 2018-11, Targeted Improvements*. The new standard establishes a right-of-use ("ROU") model that requires a lessee to recognize a ROU asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. Lessor accounting under the new standard is substantially unchanged. Additional qualitative and quantitative disclosures are also required.

The Company adopted the new standard on January 1, 2019 using the modified retrospective transition method, which applies the provisions of the standard at the effective date without adjusting the comparative periods presented. The Company adopted the following practical expedients and accounting policies elections related to this standard:

- Short-term lease accounting policy election allowing lessees to not recognize ROU assets and liabilities for leases with a term of 12 months or less;
- The option to not separate lease and non-lease components in the Company's lease contracts; and
- The package of practical expedients applied to all of its leases, including (i) not reassessing whether any expired or existing contracts are or contain leases, (ii) not reassessing the lease classification for any expired or existing leases, and (iii) not reassessing the capitalization of initial direct costs for any existing leases.

Adoption of this standard resulted in the recognition of operating lease right-of-use assets and corresponding lease liabilities of approximately $4.2 million and approximately $4.5 million, respectively, on the consolidated balance sheet as of January 1, 2019. In addition, the Company reclassified $0.2 million from leasehold improvements & equipment to finance lease right-of-use assets in connection with the adoption of ASC Topic 842. The Company's accounting for finance leases remained substantially unchanged. Disclosures related to the amount, timing and uncertainty of cash flows arising from leases are included in Note 8, Leases.

Preferred stock dividends

Prior to automatic conversion on July 29, 2019, shares of Series A Preferred Stock earned dividends at a rate of 8.0% once per year on the first, second and third anniversary of July 29, 2016, which was paid to the holders of such Series A Preferred Stock in the form of shares of the Company's common stock when converted. In addition, and subject to provisions detailed more fully in Note 12, Stockholders' Equity, shares of Series B Preferred Stock earn dividends at rates of 10%, 15% and 20% once per year on the first, second and third anniversary, respectively, of June 19, 2018. Dividends are payable to holders of the Series B Preferred Stock in the form of shares of the Company's common stock. Preferred stock dividends do not require declaration by the Board of Directors and are accrued annually as of the date the dividend is earned in an amount equal to the applicable rate of the stated value.

Beneficial conversion feature of convertible preferred stock

The Company accounts for the beneficial conversion feature on its convertible preferred stock in accordance with ASC 470-20, *Debt with Conversion and Other Options*. The Beneficial Conversion Feature ("BCF") of convertible preferred stock is normally characterized as the convertible portion or feature that provides a rate of conversion that is below market value or in-the-money when issued. The Company records a BCF related to the issuance of convertible preferred stock when issued. BCFs that are contingent upon the occurrence of a future event are recorded when the contingency is resolved.

To determine the effective conversion price, the Company first allocates the proceeds received to the convertible preferred stock and then uses those allocated proceeds to determine the effective conversion price. If the convertible instrument is issued in a basket transaction (i.e., issued along with other freestanding financial instruments), the proceeds should first be allocated to the various instruments in the basket. Any amounts paid to the investor when the transaction is consummated (e.g., origination fees, due diligence costs) represent a reduction in the proceeds received by the issuer. The intrinsic value of the conversion option is measured using the effective conversion price for the convertible preferred stock on the proceeds allocated to that instrument. The effective conversion price represents proceeds allocable to the convertible preferred stock divided by the number of shares into which it is convertible. The effective conversion price is then compared to the per share fair value of the underlying shares on the commitment date.

The BCF is recognized by allocating the intrinsic value of the conversion option to additional paid-in capital, resulting in a discount on the convertible preferred stock. This discount is accreted from the date on which the BCF is first recognized through the earliest conversion date for instruments that do not have a stated redemption date. The intrinsic value of the BCF is recognized as a deemed dividend on convertible preferred stock over the period specified in the guidance.

Income taxes

Deferred taxes are provided on a liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will not be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates.

The Company adopted the provisions of Accounting Standard Codification 740-10 and has analyzed its filing positions in 2020 and 2019 in jurisdictions where it may be obligated to file returns. The Company believes that its income tax filing position and deductions will be sustained on audit and does not anticipate any adjustments that will result in a material change to its financial position. Therefore, no reserves for uncertain income tax positions have been recorded. The Company's policy is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrual for interest or penalties as of December 31, 2020.

Since the Company incurred net operating losses in every tax year since inception, the 2014 through 2019 income tax returns are subject to examination and adjustments by the IRS for at least three years following the year in which the tax attributes are utilized.

Fair Value Measurements

As defined in ASC 820 "Fair Value Measurement", fair value measurements should be disclosed separately by three levels of the fair value hierarchy. For assets and liabilities recorded at fair value, it is the Company's policy to maximize the use of observable inputs (quoted prices in active markets) and minimized the use of unobservable inputs (the Company's assumptions) when developing fair value measurements, in accordance with the established fair value hierarchy. For a complete disclosure of the Company's fair value measurements, see Note 5 – Fair Value Measurements.

Stock-based compensation

Stock-based compensation to employees consist of stock option grants and restricted shares that are recognized in the consolidated statement of operations based on their fair values at the date of grant.

The Company accounts for equity instruments issued to non-employees in accordance with the provisions of ASC Topic 505, subtopic 50, *Equity-Based Payments to Non-Employees* based upon the fair-value of the underlying instrument. The equity instruments, consisting of stock options granted to consultants, are valued using the Black-Scholes valuation model. The Company calculates the fair value of option grants utilizing the Black-Scholes pricing model and estimates the fair value of restricted stock based upon the estimated fair value or the common stock. The amount of stock-based compensation recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. The Company accounts for forfeitures as they occur. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered stock option or warrant.

The resulting stock-based compensation expense for both employee and non-employee awards is generally recognized on a straight-line basis over the requisite service period of the award.

Basic and diluted net loss per common share

Net loss per share information is determined using the two-class method, which includes the weighted-average number of shares of common stock outstanding during the period and other securities that participate in dividends (a "participating security"). The Company considered its Preferred Stock to be participating securities because they included

rights to participate in dividends with the common stock.

Under the two-class method, basic net loss per share attributable to common stockholders is computed by dividing the net income attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. The net loss attributable to common stockholders is calculated by adjusting the net loss of the Company for the accretion on the Preferred Stock. Net losses are not allocated to preferred stockholders as they do not have an obligation to share in the Company's net losses. In periods with net income attributable to common stockholders, the Company would allocate net income first to preferred stockholders based on dividend rights under the Company's certificate of incorporation and then to preferred and common stockholders based on ownership interests. Diluted net loss per share attributable to common stockholders is computed using the more dilutive of (1) the two-class method or (2) the if-converted method.

During the years ended December 31, 2020 and 2019, diluted earnings per common share is the same as basic earnings per common share because, as the Company incurred a net loss during each period presented, the potentially dilutive securities from the assumed exercise of all outstanding stock options, warrants and conversion of preferred stock, would have an anti-dilutive effect. The reconciliation of the diluted shares as of December 31, 2020 and 2019 are as follows (in thousands):

	As of December 31,	
	2020	**2019**
Stock options	22,551	17,529
Preferred Stock and accrued dividend upon conversion	8,722	9,154
Warrants	1,328	5,397
Total	32,601	32,080

Revenue recognition

Pursuant to Topic 606, the Company recognizes revenue to depict the transfer of promised goods or services to a customer in an amount that reflects the consideration to which the entity expects to be intitled in exchange for those goods or services. To achieve this core principle, Topic 606 outlines a five-step process for recognizing revenue from customer contracts that includes i) identification of the contract with a customer, ii) identification of the performance obligations in the contract, iii) determining the transaction price, iv) allocating the transaction price to the separate performance obligations in the contract, and v) recognizing revenue associated with performance obligations as they are satisfied.

At contract inception, the Company assesses the goods or services promised within each contract and assess whether each promised good or service is distinct and determine those that are performance obligations. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when the performance obligation is satisfied.

For the years ended December 31, 2020 and 2019, the Company's revenues primarily consist of a research grant to provide research and development services to the Cystic Fibrosis Foundation ("CFF"). The grant contract has a single performance obligation that is recognized over time as the services are performed. There are no contract assets or liabilities associated with this grant. As certain contract performance obligations in this contract were completed, it was the Company's only contract with revenue from a customer for 2019 and disaggregation of revenue is not required. The Company had approximately $125.0 thousand and $89.8 thousand of CFF research grant revenue for the years ended December 31, 2020 and 2019, respectively.

On December 12, 2019, the Company entered into a feasibility study agreement (the "Agreement") with Genentech, Inc. ("Genentech"). This feasibility study will involve the development of oral formulations using the Company's LNC platform delivery technology, which enables the development of a wide range of difficult-to-deliver molecules. Under the terms of the Agreement, Genentech paid the Company a total of $100.0 thousand for three molecules, or approximately $33.3 thousand per molecule, which will be recognized upon the Company fulfilling its obligations for each molecule under the Agreement. The Agreement has a single performance obligation that is recognized over time as the services are performed. There are no contract assets or liabilities associated with this Agreement. As certain Agreement performance obligations in this agreement were completed, disaggregation of revenue is not required. As of December 31, 2020, the Company completed the first of three molecules and the Company recognized approximately $33.3 thousand of revenue for the year ended December 31, 2020. The Company is scheduled to complete the remaining two molecules during 2021.

Collaboration Agreements

The Company assess whether its collaboration agreements are subject to ASC Topic 808, *Collaborative Arrangements* (Topic 808) based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. To the extent that the arrangement falls within the scope of Topic 808, the Company will apply by analogy the unit of account guidance under Topic 606 to identify distinct performance obligations, and then determine whether a customer relationship exists for each distinct performance obligation. If the Company determines a performance obligation within the arrangement is with a customer, the Company applies the guidance in Topic 606. If a portion of a distinct bundle of goods or services within an arrangement is not with a customer, then the unit of account is not within the scope of Topic 606, and the recognition and measurement of that unit of account shall be based on analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational, and consistently applied accounting policy election.

The terms of such arrangements typically include payments to the Company for one or more of the following: up-front fees; development and regulatory payments; product supply services; research and development cost reimbursements; profit-sharing arrangements; and royalties on certain products if they are successfully commercialized. As part of the accounting for these arrangements, the Company develops assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. These key assumptions may include forecasted revenues, clinical development timelines and costs, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Up-front License Fees: If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company would recognize revenues from nonrefundable up-front fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license, which generally would occur at or near the inception of the contract. For licenses that are bundled with other promises, the Company would utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenues from nonrefundable up-front fees. The Company will evaluate the measure of progress at the end of each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Research and Development Milestone Payments: At the inception of each arrangement that includes development milestone payments, the Company will evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until uncertainty associated with the approvals has been resolved. The transaction price is then allocated to each performance obligation, on a relative standalone selling price basis, for which the Company will recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achieving such development and regulatory milestones and any related variable consideration constraint, and if necessary, adjust our estimate of the overall transaction price. Any such

adjustments are recorded on a cumulative catch-up basis.

Research and Development Cost Reimbursements: The Company's collaboration arrangements may include promises of future clinical development and drug safety services, as well as participation on certain joint committees. When such services are provided to a customer or partner, and they are distinct from the licenses provided to the Company's collaboration partners, these promises are accounted for as a separate performance obligation which the Company estimates using internal development costs incurred and projections through the term of the arrangements. The Company records revenues for these services as the performance obligations are satisfied over time based on measure of progress. However, if the Company concludes that its collaboration partner is not a customer for those collaborative research and development activities, it presents such payments as a reduction of research and development expenses.

Research and Development Arrangement: Under the terms of our research and development agreement with the Cystic Fibrosis Foundation Therapeutics, Inc. ("CFF Agreement"), the Company did not account for this arrangement in accordance with Topic 606. However, the Company has determined that it is a partner under a collaboration agreement as it shares in the risks and rewards that would be received if the product is successful and commercialized. Therefore the funds received under the terms of this agreement will be recorded as reimbursements of research and development costs and reduce the research and development expenses in the Company's Statements of Operations and Comprehensive Income/(Loss). The Company records the reimbursements for certain materials and other research and development costs associated with the agreement when it is probable that a significant reversal in the amount of cumulative costs have been recognized. As of December 31, 2020, the Company recognized approximately $73.4 thousand of reimbursed research and development costs associated with the CFF Agreement. For a complete disclosure of the CFF Agreement, see Note 9 – Collaboration Agreements, License and other Research and Development Agreements.

Research and development expenses

Research and development expenses primarily consist of costs associated with the preclinical and clinical development of our product candidate portfolio, including the following:

- external research and development expenses incurred under arrangements with third parties, such as contract research organizations ("CROs") and other vendors and contract manufacturing organizations ("CMOs") for the production of drug substance and drug product; and

- employee-related expenses, including salaries, benefits and share-based compensation expense.

Research and development expenses also include costs of acquired product licenses and related technology rights where there is no alternative future use, costs of prototypes used in research and development, consultant fees and amounts paid to certain of our collaborative partners.

All research and development expenses are charged to operations as incurred in accordance with FASB ASC Topic 730, Research and Development. The Company accounts for non-refundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received, rather than when the payment is made.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, the Company is required to estimate its accrued expenses. 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. Certain of the Company's service providers invoice the Company monthly in arrears for services performed or when contractual milestones are met. The Company makes estimates of its accrued expenses as of each balance sheet date in its financial statements based on facts and circumstances known to the Company at that time. The Company periodically confirms the accuracy of its estimates with the service providers and adjust if necessary. The significant estimates in the Company's accrued research and development expenses are related to expenses incurred with respect to CROs, CMOs and other vendors in connection with research and development and manufacturing activities.

The Company bases its expense related to CROs and CMOs on its estimates of the services received and efforts expended pursuant to quotations and contracts with such vendors that conduct research and development and manufacturing activities on its behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to the Company's vendors will exceed the level of services provided and result in a prepayment of the applicable research and development or manufacturing expense. In accruing service fees, the Company estimates the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from its estimate, the Company adjust the accrual or prepaid expense accordingly. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period. There have been no material changes in estimates for the periods presented.

Patent expenses

Legal fees and other direct costs incurred in obtaining and protecting patents are also expensed as incurred and are included in general and administrative expenses in the consolidated statements of operations.

Other comprehensive income/(loss)

Other comprehensive income/(loss) consists of net gains/(losses) and unrealized losses on marketable securities available-for-sale and is presented in the Consolidated Statements of Operations.

Recently adopted accounting pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2016-13, "Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments". The standard represents a significant change to the impairment model for most financial assets that are measured at amortized costs and certain other instruments from an incurred loss model to an expected loss model which will be based on an estimate of current expected credit loss ("CECL") and provides targeted improvements on evaluating impairment and recording credit losses on available-for-sale debt securities through an allowance account. The guidance is effective for public entities in fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. The adoption did not have a material impact on our consolidated financial statements.

In November 2019, the FASB Issued ASU 2019-11, "Codification Improvements to Topic 326, Financial Instruments – Credit Losses". The amendments in this standard represent changes to clarify, correct errors in, or improve the Codification. The amendments make the Codification easier to understand and easier to apply by eliminating inconsistencies and providing clarifications. This standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The adoption did not have a material impact on our consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, "Changes to Disclosure Requirements for Fair Value Measurements", which will improve the effectiveness of disclosure requirements for recurring and nonrecurring fair value measurements. The standard removes, modifies, and adds certain disclosure requirements, and is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The adoption did not have a material impact on our consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, "Collaboration Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606", to clarify when ASC 606 should be used for collaborative arrangements when the counterparty is a customer. The Guidance precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from the contracts with the customers if the counterparty is not a customer for that transaction. The guidance is effective for public entities in fiscal years beginning after December 15, 2019, and interim period therein. The adoption did not have a material impact on our consolidated financial statements in 2020, see Note 9 – Collaboration Agreements, License and other Research and Development Agreements.

Recent accounting pronouncements not yet adopted

In December 2019, the FASB Issued ASU 2019-12, "Income Taxes, (Topic 740): Simplifying the Accounting for Income Taxes". This standard removes certain exceptions to the general principles and improves consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. This standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company is currently evaluating the impact this standard will have on its consolidated financial statements.

Note 4 – Cash, Cash Equivalents, Restricted Cash and Marketable Securities

The Company considers all highly liquid financial instruments with original maturities of three months or less when purchased to be cash and cash equivalents and all investments with maturities of greater than three months from date of purchase are classified as marketable securities. Cash and cash equivalents consisted of cash in bank checking and savings accounts, money market funds and short-term U.S. treasury bonds that mature within three months of settlement date.

Cash, Cash Equivalents and Restricted Cash

The Company presents restricted cash with cash and cash equivalents in the Consolidated Statements of Cash Flows. Restricted cash represents funds the Company is required to set aside to cover building operating leases and other purposes.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported in the Consolidated Balance Sheets to the total of the amounts in the Consolidated Statements of Cash Flows as of December 31, 2020, December 31, 2019 and December 31, 2018 (in thousands):

	December 31, 2020	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 12,432	$ 22,170	$ 12,447
Restricted cash included in current/long term assets	336	586	561
Cash, cash equivalents and restricted cash in the statements of cash flows	$ 12,768	$ 22,756	$ 13,008

Marketable Securities

The Company has classified its investments in marketable securities as available-for-sale and as a current asset. The Company's investments in marketable securities are carried at fair value, with unrealized gains and losses included as a separate component of stockholders' equity. Unrealized gains and losses are classified as other comprehensive income (loss) and costs are determined on a specific identification basis. Realized gains and losses from our marketable securities are recorded in other income, net. For the years ended December 31, 2020 and 2019, the Company recorded unrealized gains/(losses) of approximately $237.5 thousand and $0.9 thousand, respectively, and reclassed approximately $8.5 thousand to net loss from operations from the sale of certain securities during 2020. As of December 31, 2020 and 2019, the Company had net accumulated unrealized gains of approximately $228.2 thousand and net accumulated unrealized losses of approximately $0.9 thousand, respectively.

The following tables summarizes the Company's marketable securities for the year ended December 31, 2020 consisted of the following (in thousands):

	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
U.S. Treasury Bonds	$ 18,293	$ 136	$ —	$ 18,429
U.S. Government Notes	22,148	82	—	22,230
Corporate Debt Securities	4,303	3	—	4,306
State and Municipal Bonds	1,275	7	—	1,282
Total marketable securities	$ 46,019	$ 228	$ —	$ 46,247

Maturities of debt securities classified as available-for-sale were as follows at December 31, 2020 (in thousands):

	Fair Value	Net Carrying Amount
Due within one year	$ 31,438	$ 31,602
Due after one year through five years	14,809	14,845
	$ 46,247	$ 46,447

The following tables summarizes the Company's cash, cash equivalents and marketable securities for the year ended December 31, 2019 consisted of the following (in thousands):

	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Fair Value
Cash and cash equivalents	$ 22,169	$ 1	$ —	$ 22,170
U.S. Treasury Bonds	$ 4,003	$ —	$ (1)	$ 4,002

Corporate Debt Securities	1,604	—	(1)	1,603
Total marketable securities	$ 5,607	$ —	$ (2)	$ 5,605
Total cash, cash equivalents and marketable securities	$ 27,776	$ 1	$ (2)	$ 27,775

Maturities of debt securities classified as available-for-sale were as follows at December 31, 2019 (in thousands):

	Fair Value	Net Carrying Amount
Due within one year	$ 5,002	$ 5,019
Due after one year through five years	603	607
	$ 5,605	$ 5,626

The Company determined that the unrealized gains and (losses) are deemed to be temporary as of December 31, 2020. Unrealized gains and (losses) generally are the result of increases in the risk premiums required by market participants rather than an adverse change in cash flows for a fundamental weakness in the credit quality of the issuer or underlying assets. The Company has the ability and intent to hold these investments until maturity. The Company does not consider the investment in marketable securities to be other-than-temporarily impaired at December 31, 2020.

Note 5 - Fair Value Measurements

The Company uses the fair value hierarchy to measure the value of its financial instruments. The fair value hierarchy is based on inputs to valuation techniques that are used to measure fair value that are either observable or unobservable. Observable inputs reflect assumptions market participants would use in pricing an asset or liability based on market data obtained from independent sources, while unobservable inputs reflect a reporting entity's pricing based upon its own market assumptions. The basis for fair value measurements for each level within the hierarchy is described below:

- Level 1 – Quoted prices for identical assets or liabilities in active markets.
- Level 2 – Quoted prices for identical or similar assets and liabilities in markets that are not active; or other model-derived valuations whose inputs are directly or indirectly observable or whose significant value drivers are observable.
- Level 3 – Valuations derived from valuation techniques in which one or more significant inputs to the valuation model are unobservable and for which assumptions are used based on management estimates.

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

The carrying amounts of certain cash and cash equivalents, current portion of restricted cash, marketable securities, prepaid expenses and other current assets, accounts payable, current portion of lease liability and accrued expenses approximate fair value due to the short-term nature of these instruments.

A summary of the assets and liabilities carried at fair value in accordance with the hierarchy defined above is as follows (in thousands):

		Fair Value Hierarchy		
December 31, 2020	**Total**	**(Level 1)**	**(Level 2)**	**(Level 3)**
Assets				
Marketable Securities:				
U.S. Treasury Bonds	$ 18,429	$ 18,429	$ —	$ —
U.S. Government Notes	22,230	—	22,230	—
Corporate Debt Securities	4,306	—	4,306	—
State and Municipal Bonds	1,282	—	1,282	—
Total	$ 46,247	$ 18,429	$ 27,818	$ —

		Fair Value Hierarchy		
December 31, 2019	**Total**	**(Level 1)**	**(Level 2)**	**(Level 3)**
Assets				
Cash and cash equivalents	$ 22,170	$ 22,170	$ —	$ —
Marketable Securities:				
U.S. Treasury Bonds	4,002	4,002	—	—
Corporate Debt Securities	1,603	—	1,603	—
Total	$ 27,775	$ 26,172	$ 1,603	$ —

U.S. treasury bonds are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices for identical assets in active markets. Marketable securities consisting of U.S. government notes, corporate debt securities and state and municipal bonds are classified as Level 2 and are valued using quoted market prices in markets that are not active.

Note 6 – Leasehold Improvements and Equipment

Leasehold improvements and equipment, summarized by major category, consist of the following for the years ended December 31, 2020 and 2019 (in thousands):

	December 30, 2020	December 31, 2019
Lab equipment	$ 1,443	$ 1,437
Leasehold improvements	878	878
Total	2,321	2,315
Less: accumulated depreciation and amortization	797	566
Leasehold improvements and equipment, net	$ 1,524	$ 1,749

Depreciation and amortization expense for the years ended December 31, 2020 and 2019 was approximately $231.1 thousand and $206.0 thousand, respectively. Due to the

adoption of the new lease accounting pronouncement in January 2019 and the reclass of certain right-of-use assets upon adoption, the Company reclassed $559 thousand and $72 thousand of assets and related accumulated depreciation, respectively. In addition, in July 2019, the Company recorded an asset write-off of approximately $14 thousand, including $7 thousand of related accumulated depreciation.

Note 7 – Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities, summarized by major category, consist of the following for years ended December 31, 2020 and 2019 (in thousands):

	As of December 31,	
	2020	2019
Payroll and incentives	$ 1,094	$ 978
General and administrative expenses	280	441
Research and development expenses	778	421
Deferred revenue and other deferred liabilities *	643	100
Total	$ 2,795	$ 1,940

* At December 31, 2020, approximately $576.6 thousand is the remaining balance of the CFF Agreement's deferred liability and approximately $66.6 thousand is deferred revenue related to the Genentech feasibility study agreement. The $100.0 thousand of deferred revenue at December 31, 2019 is the upfront payment for the Genentech feasibility study agreement.

Note 8 – Leases

The Company has various lease agreements with terms up to 10 years, including leases of office space, a laboratory and manufacturing facility, and various equipment. Some leases include purchase, termination or extension options for one or more years. These options are included in the lease term when it is reasonably certain that the option will be exercised.

Operating lease obligations

On November 1, 2013, the Company entered into a 7-year lease for office space in Bedminster, New Jersey which commenced in June, 2014 at a monthly rent of approximately $13,000, increasing to approximately $14,000 per month toward the end of the term, which is May 2021. The Company was obligated to provide an initial security deposit of $300,000 to obtain the office lease space. As of December 31, 2020, the total deposit had been returned to the Company.

On September 23, 2020, the Company entered into an amendment to the Bedminster lease. Pursuant to the amendment, the Company will lease an additional 3,034 rentable square feet ("Expansion Premises"). The amendment becomes effective upon the date on which the landlord delivers to the Company the Expansion Premises, which is expected to occur in the second quarter of 2021, and extends the term of the lease for seven years from such date. There is no renewal option, no security deposit, no residual value or significant restrictions or covenants other than those customary in such arrangements. Except as expressly provided, all other terms, covenants, conditions and agreements as set forth in the lease will remain unchanged and in full force and effect. The total lease commitment over the seven-year extension period is approximately $1.8 million.

On December 15, 2016, the Company entered into a 10-year, 3-month lease to consolidate our locations while expanding our laboratory and manufacturing facilities. The lease began August 2017. The monthly rent will start at approximately $43,000 increasing to approximately $64,000 in the final year. To obtain the laboratory and facility site, the Company was obligated to provide an initial security deposit of $586,000. This deposit was subsequently reduced to $286,000. It can be further reduced by $86,000 on the next anniversary of the rent commencement date, after which it will remain at $200,000 for the balance of the lease term.

The assets and liabilities from operating and finance leases are recognized at the lease commencement date based on the present value of remaining lease payments over the lease term using the Company's incremental borrowing rates or implicit rates, when readily determinable. Short-term leases, which have an initial term of 12 months or less, are not recorded on the balance sheet.

The Company's operating leases do not provide an implicit rate that can readily be determined. Therefore, the Company uses a discount rate based on its incremental borrowing rate, which is determined using the average of borrowing rates explicitly stated in the Company's finance leases.

The Company incurred lease expense for its operating leases of approximately $813.7 thousand for the years ended December 31, 2020 and 2019. The Company incurred amortization expense on its operating lease right-of-use assets of approximately $484.6 thousand and $452.1 thousand for the years ended December 31, 2020 and 2019, respectively.

Finance Leases

The Company incurred interest expense on its finance leases of approximately $6.7 thousand and $11.7 thousand for the years ended December 31, 2020 and 2019, respectively. The Company incurred amortization expense on its finance lease right-of-use assets of approximately $59.0 thousand and $122.8 thousand for the years ended December 31, 2020 and 2019, respectively.

The following table presents information about the amount and timing of liabilities arising from the Company's operating leases, excluding the Expansion Premises of the amended Bedminster lease which the Company has not taken control of as of December 31, 2020, and finance leases as of December 31, 2020 (in thousands):

Maturity of Lease Liabilities	Operating Lease Liabilities	Finance Lease Liabilities
2021	$ 685	$ 34
2022	645	19
2023	677	2
2024	710	-
2025	745	-
Thereafter	1,458	-
Total undiscounted operating lease payments	$ 4,920	$ 55
Less: Imputed interest	1,224	-
Present value of operating lease liabilities	$ 3,696	$ 55

Weighted average remaining lease term in years	6.7	1.7
Weighted average discount rate	8.4%	8.1%

The following table presents information about the amount and timing of liabilities arising from the Company's operating and finance leases as of December 31, 2019 (in thousands):

Maturity of Lease Liabilities	Operating Lease Liabilities	Finance Lease Liabilities
2020	$ 753	$ 60
2021	685	34
2022	645	19
2023	677	2
2024	710	-
Thereafter	2,203	-
Total undiscounted operating lease payments	$ 5,673	$ 115
Less: Imputed interest	1,554	6
Present value of operating lease liabilities	$ 4,119	$ 109
Weighted average remaining lease term in years	7.5	2.2
Weighted average discount rate	8.4%	7.8%

Note 9 - Collaboration Agreements, License and Other Research and Development Agreements

Cystic Fibrosis Foundation Therapeutics Development Award

On November 19, 2020, the Company entered into an award agreement (the "Agreement") with Cystic Fibrosis Foundation ("CFF"), pursuant to which it received a Therapeutics Development Award of up to $4.2 million (the "Award") (of which $484,249 had been previously received) to support the preclinical development (the "Development Program") of the Company's MAT2501 product candidate (the "Product"), a lipid nanocrystal oral formulation of the broad-spectrum aminoglycoside amikacin, for the treatment of pulmonary non-tubercular mycobacteria infections and other pulmonary diseases (the "Field").

The first payment under the Agreement, in the amount of $650.0 thousand, became due upon execution of the Agreement. The Company invoiced the CFF in November 2020 and payment was subsequently received in February 2021. At December 31, 2020, the related receivable of $650.0 thousand is included in prepaid expenses and other current assets and the related deferred liability balance of $576.6 thousand is included in accrued expense and other current liabilities. The remainder of the Award will be paid to the Company incrementally in installments upon the achievement of certain milestones related to the development program and progress of the Development Program, as set forth in the Agreement.

If the Company ceases to use commercially reasonable efforts directed to the development of MAT2501 in the Field, (an "Interruption") and fails to resume the development of the Product after receiving from CFF notice of an Interruption, then the Company must either repay the amount of the Award actually received by the Company, or grant to CFF (1) an exclusive (even as to the Company), worldwide, perpetual, sublicensable license under technology developed under the Agreement that covers the Product for use in treating infections in CF patients (the "CF Field"), and (2) a non-exclusive, worldwide license under certain background intellectual property covering the Product, to the extent necessary to commercialize the Product in the CF Field.

Pursuant to the terms of the Agreement, the Company is obligated to make royalty payments to CFF contingent upon commercialization of the Product in the Field up to a maximum of five (5) times the Award or approximately $21.2 million (the "Royalty Cap"), payable in three equal annual installments following the first commercial sale of the Product, the first of which is due within 90 days following the first commercial sale of the Product. The Company may also be obligated to make a payment to CFF if the Company transfers, sells or licenses the Product in the CF Field, or if the Company enters into a change of control transaction which will be applied against the Royalty Cap. In addition, the Company is also obligated to make up the two royalty payments of CFF of the approximately $4.2 million each, due in the calendar years in which specific net sales milestones are achieved.

The term of the Agreement commenced on November 19, 2020 and expires on the earlier of the date on which the Company has paid CFF all of the fixed royalty payments set forth therein, the effective date of any license granted to CFF following an Interruption, or upon earlier termination of the Agreement. Either CFF or the Company may terminate the agreement for cause, which includes the Company's material failure to achieve certain development milestones. The Company's payment obligations survive the termination of the Agreement.

The Company concluded that the CFF award is in the scope of ASC 808. Accordingly, as discussed in Note 3, the award amounts received from CFF upon achievement of certain milestones are recognized as credits to research and development expenses in the period the Development Program's expenses are incurred. During the year ended December 31, 2020, the Company recognized $73.4 thousand, as credits to research and development expenses related to the CFF award. In addition, the Company concluded under the guidance in ASC 730 that it does not have an obligation to repay funds received once related research and development expenses are incurred.

Genentech Feasibility Study Agreement

On December 12, 2019, the Company entered into a feasibility study agreement (the "Agreement") with Genentech, Inc. ("Genentech"). This feasibility study agreement will involve the development of oral formulations using the Company's LNC platform delivery technology, which enables the development of a wide range of difficult-to-deliver molecules. Under the terms of the Agreement, Genentech shall pay to the Company a total of $100.0 thousand for three molecules, or approximately $33.3 thousand per molecule, which will be recognized upon the Company fulfilling its obligations for each molecule under the Agreement. On December 13, 2019, per Genentech's request, the Company billed Genentech for the total $100 thousand and recorded the upfront consideration as deferred revenue, which is recorded in accrued expenses on the consolidated balance sheets, and will recognize it over the term of the contract performance obligation period. As of December 31, 2020, the Company completed the first of three molecules and the Company recognized approximately $33.3 thousand of Genentech revenue for the year ended December 31, 2020. The Company did not complete any contract performance obligations during 2019.

Other Research and development agreements

The Company has financial obligations resulting from Cooperative Research and Development Agreements ("CRADAs") entered into with the with the National Institute of Allergy and Infectious Diseases ("NIH") as follows:

- On February 19, 2016, the Company agreed to provide funds in the amount of $200,000 per year under a CRADA to support NIH investigators in the conduct of clinical research to investigate the safety, efficacy, and pharmacokinetics of LNC platform drug products in patients with fungal, bacterial, or viral infections. The initial term of the CRADA was three years. On April 16, 2019, the Company renewed the CRADA for an additional three years with an annual funding commitment of $200,000.

- On April 2, 2019, the Company agreed to provide funds in the amount of $157,405 per year under a CRADA to support NIH investigators in the conduct of clinical research to investigate the safety, efficacy, and pharmacokinetics of LNC platform drug products in patients with fungal, bacterial, or viral infections. The term of the CRADA is three years.

License agreement

Through the acquisition of Aquarius, the Company acquired a license from Rutgers University, The State University of New Jersey (successor in interest to the University of Medicine and Dentistry of New Jersey) for the LNC platform delivery technology. The Amended and Restated Exclusive License Agreement provides for, among other things, the payment of (1) royalties on a tiered basis between low single digits and the mid-single digits of net sales of products using such licensed technology, (2) a one-time sales milestone fee of $100,000 when and if sales of products using the licensed technology reach the specified sales threshold and (3) an annual license fee of initially $10,000, increasing to the current fee amount of $50,000 over the term of the license agreement.

Note 10 – Commitments

Royalty payment rights

On September 12, 2016 the Company conducted a final closing of a private placement offering to accredited investors of shares of the Company's Series A Preferred Stock. As part of this offer, the investors received royalty payment rights if and when the Company generates sales of its MAT2203 or MAT2501 product candidates. Pursuant to the terms of the Series A Certificate of Designation, the Company may be required to pay royalties of up to $35 million per year. If and when the Company obtains FDA or the European Medicines Agency ("EMA") approval of MAT2203 and/or MAT2501, which the Company does not expect to occur before 2023, if ever, and/or if the Company generates sales of such products, or the Company receives any proceeds from the licensing or other disposition of MAT2203 or MAT2501, the Company is required to pay to the holders of the Series A Preferred Stock, subject to certain vesting requirements, in the aggregate, a royalty (the "Royalty Payment Rights") equal to (i) 4.5% of Net Sales (as defined in the Series A Certificate of Designation), subject in all cases to a cap of $25 million per calendar year, and (ii) 7.5% of Licensing Proceeds (as defined in the Series A Certificate of Designation), subject in all cases to a cap of $10 million per calendar year. The Royalty Payment Rights will expire when the patents covering the applicable product expire, which is currently expected to be in 2033.

Employment agreements

The Company also has employment agreements with certain employees which require the funding of a specific level of payments, if certain events, such as a change in control, termination without cause or retirement, occur.

Acquisition of Aquarius Biotechnologies, Inc. (now known as Matinas BioPharma Nanotechnologies, Inc.)

Pursuant to the terms of the merger agreement with Aquarius Biotechnologies, Inc., the Company may be required to issue up to an additional 3,000,000 shares of our common stock upon the achievement of certain milestones. The milestone consideration consists of (i) 1,500,000 shares issuable upon the dosing of the first patient in a phase III trial sponsored by us for a product utilizing Aquarius' proprietary LNC platform delivery technology and (ii) 1,500,000 shares issuable upon FDA approval of the first NDA submitted by us for a product utilizing Aquarius' proprietary LNC platform delivery technology. The Company concluded that the contingent share issuance represented equity settled contingent consideration and have recorded the amounts to equity since inception. None of these milestones have been reached, and accordingly, as of December 31, 2020 no additional shares have been issued.

Other normal business operating agreements

In addition, in the course of normal business operations, the Company enters into agreements with contract service providers to assist in the performance of research & development and manufacturing activities. Expenditures to these third parties represent significant costs in clinical development and may require upfront payments and long-term commitments of cash. Subject to required notice periods and obligations under binding purchase orders, the Company can elect to discontinue the work under these agreements at any time.

Note 11 – Income Taxes

The Company utilizes the liability method of accounting for deferred income taxes. Under this method, deferred tax liabilities and assets are recognized for the expected future tax consequences of temporary differences between the carrying amounts and the tax basis of assets and liabilities. A valuation allowance is established against deferred tax assets when, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company's policy is to record interest and penalties on uncertain tax positions as income tax expense. As of December 31, 2020 and 2019, the Company does not believe any material uncertain tax positions were present. Accordingly, interest and penalties have not been accrued due to an uncertain tax position.

The components of the income tax provision are as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Current expense (benefit):		
Federal	$ -	$ -
State	-	-
Foreign	-	-
Total current expense (benefit):	$ -	$ -
Deferred expense (benefit):		
Federal	$ -	$ -
State	-	-
Foreign	-	-
Total deferred expense (benefit):	$ -	$ -
Total income tax expense (benefit):	$ -	$ -

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

	Year Ended December 31,	
	2020	2019
Income at US Statutory Rate	21.00%	21.00%
State Taxes, net of Federal benefit	2.95%	3.82%
Permanent Differences	-1.28%	-0.88%
Tax Credits	0.75%	1.06%
Valuation Allowance	-24.53%	-29.92%
Discrete items	1.11%	4.92%
	0.00%	0.00%

The Company has no current income taxes payable other than certain state minimum taxes which are included in general and administrative expenses.

Significant components of the Company's deferred tax assets (liabilities) for 2020 and 2019 consist of the following (in thousands):

	Year Ended December 31,	
	2020	2019
Share-based Compensation	$ 3,220	$ 2,611
Depreciation and Amortization	(119)	(219)
Accrued Liability	307	275
Net Operating Loss Carry-forwards	19,927	15,587
R&D Credit Carryforwards	2,264	1,881
Other	(10)	(27)
IPR&D	(848)	(848)
ROU Asset	(921)	(1,057)
ROU Liability	1,045	1,158
Total Deferred tax assets	$ 24,865	$ 19,361
Valuation allowance	(25,206)	(19,702)
Net deferred tax asset (liability)	$ (341)	$ (341)

On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security (CARES) Act was signed into law making several changes to the Internal Revenue Code. The changes include, but are not limited to: allowing companies to carryback certain net operating losses, and increasing the amount of net operating loss carryforwards that corporations can use to offset taxable income. The tax law changes in the Act did not have a material impact on the Company's income tax provision.

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible, and is impacted by the Company's ability to carryforward losses to years in which the Company has taxable income. Due to the Company's history of losses and lack of other positive evidence to support taxable income, the Company has recorded a valuation allowance against those deferred tax assets that are not expected to be realized. The valuation allowance was approximately $25.2 million and approximately $19.7 million as of December 31, 2020 and 2019, respectively, representing an increase of approximately $5.5 million.

As of December 31, 2020, the Company had Federal net operating loss carryforwards of approximately $38.1 million which will begin to expire in 2032. In addition, the Company has federal net operating loss carryforwards of approximately $45.0 million which have an indefinite carryforward period. The Company also had federal and state research and development tax credit carryforwards of approximately $2.3 million. The federal net operating loss and tax credit carryforwards will expire at various dates beginning in 2033, if not utilized. The difference between the statutory tax rate and the effective tax rate is primarily attributable to the valuation allowance offsetting deferred tax assets.

Utilization of the net operating losses and general business tax credits carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986 due to changes in ownership of the Company that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating losses and general business tax credits carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. The Company has not completed a study to determine whether it had undergone an ownership change since the Company's inception

Sale of net operating losses (NOLs)

The Company recognized approximately $1.1 million and $1.0 million for the years ended December 31, 2020 and 2019, respectively, in connection with the sale of certain State of New Jersey Net Operating Losses ("NOL") and Research and Development ("R&D") tax credits to a third party under the New Jersey Technology Business Tax Certificate Transfer Program. In addition, the Tax Cuts and Jobs Act, signed into law on December 22, 2017 imposes significant additional limitations on the deductibility of interest and limits net operating loss (NOL) deductions to 80% of net taxable income for losses arising in taxable years beginning after December 31, 2017. This NOL limitation has currently been suspended for years 2018 through 2020 as a result of the CARES Act.

Note 12 – Stockholders' Equity

At-The-Market Equity Offering

On July 2, 2020, the Company entered into an At-The-Market ("ATM") Sales Agreement (the "Sales Agreement") with BTIG, LLC ("BTIG"), pursuant to which the Company may offer and sell, from time to time, through BTIG, as sales agent and/or principal, shares of its common stock having an aggregate offering price of up to $50,000,000, subject to certain limitations on the amount of common stock that may be offered and sold by the Company set forth in the Sales Agreement. BTIG will be paid a 3% commission on the gross proceeds from each sale. The Company may terminate the Sales Agreement at any time; BTIG may terminate the Sales Agreement in certain limited circumstances. As of December 31, 2020, the Company did not sell any shares of its common stock under the ATM Sales Agreement. During January 2021, BTIG sold 3,023,147 shares of the Company's common stock generating gross proceeds of approximately $5.8 million and net proceeds of approximately $5.6 million, after deducting BTIG's commission on gross proceeds.

Common Stock

On January 14, 2020, the Company closed on an underwritten public offering of 32.3 million shares of its common stock at a purchase price of $1.55 per share. The Company generated gross proceeds of approximately $50.0 million and net proceeds of approximately $46.7 million, after deducting underwriting discounts and commissions and other estimated offering expenses. In addition, the Company granted the underwriters a 30-day option to purchase up to approximately 4.8 million additional shares of its common stock on the same terms and conditions. No additional shares of the Company's common stock were sold pursuant to this option.

On March 19, 2019, the Company closed an underwritten public offering of its common stock. This offering was made pursuant to an underwriting agreement between the Company and BTIG, LLC. The offering resulted in the sale of 27,272,727 shares to the public at a price of $1.10 per share. The Company generated gross proceeds of $30.0 million. Net proceeds after deducting underwriting discounts and commissions and other estimated offering expenses are approximately $27.8 million. In addition, the Company granted the underwriters a 30-day option (the "option") to purchase up to an additional 4,090,909 shares of common stock subject to the same terms and conditions. On March 28, 2019, an additional 2,199,259 shares were sold pursuant to the option at a price of $1.10 per share, resulting in net proceeds to the Company of approximately $2.3 million.

Preferred Stock

In accordance with the Certificate of Incorporation, the Company is authorized to issue 10,000,000 preferred shares at a par value of $0.001. In connection with a private placement of Series A Preferred Stock, on July 26, 2016, the Company filed the Series A Certificate of Designation with the Secretary of the State of Delaware to designate the preferences, rights and limitations of the Series A Preferred Stock. Pursuant to the Series A Certificate of Designation, the Company designated 1,600,000 shares of the Company's previously undesignated preferred shares as Series A Preferred Stock. In connection with a public offering of Series B Preferred Stock, on June 19, 2018, the Company filed the Series B Certificate of Designation with the Secretary of the State of Delaware to designate the preferences, rights and limitations of the Series B Preferred Stock. Pursuant to the Series B Certificate of Designation, the Company designated 8,000 shares of the Company's previously undesignated preferred shares as Series B Preferred Stock.

Series B Preferred Stock

On June 19, 2018, the Company entered into a placement agency agreement with ThinkEquity, a Division of Fordham Financial Management, Inc., as placement agent, relating to the offering, issuance and sale of up to 8,000 shares of the Company's Series B Convertible Preferred Stock, par value $0.0001 per share with a stated value of $1,000 per share which are convertible into an aggregate of up to 16,000,000 shares of the Company's common stock at an initial conversion price of $0.50 per share. The offering also included up to an additional 7,200,000 shares of common stock issuable upon payment of dividends under the Series B Preferred Stock. The offering closed on June 21, 2018 raising a gross amount of $8 million with net proceeds of $7.1 million after deducting issuance costs. The placement agent received 7% commission on the gross proceeds, 1% of the gross proceeds to cover non-accountable expenses and 240,000 warrants fair valued at approximately $89,000 treated as a reduction to gross proceeds, that are exercisable over a 5-year period at an exercise price of $0.75 per share.

As of December 31, 2020 and 2019, there were 4,361 shares 4,577 shares, respectively, of Series B Preferred Stock outstanding.

Conversion:

Optional Conversion. Subject to the Beneficial Ownership Limitation (defined below), each share of Series B Preferred Stock will be convertible into shares of the Company's common stock at any time at the option of the holder at an initial conversion price of $0.50 per share subject to adjustment for reverse splits, stock combinations and similar changes as provided in the Certificate of Designation. Based on the current conversion price and number of shares outstanding, the Series B Preferred Stock is convertible into 8,722,000 shares of common stock. Dividends will not accrue and will not be paid following optional conversion. During the years ended December 31, 2020 and 2019 216 shares and 242 shares, respectively, of Series B preferred stock were converted into shares of common stock.

Automatic Conversion. Subject to the Beneficial Ownership Limitation described below, each share of Series B Preferred Stock shall automatically convert into 2,000 shares of the Company's common stock at an initial conversion price of $0.50 per share upon the earlier of (i) the first FDA approval of one of our product candidates, (ii) the 36-month anniversary of the of the filing of the Certificate of Designation for the Series B Preferred Stock with the Secretary of State of Delaware (the "COD Effective Date" which is June 19, 2018) or (iii) the consent to conversion by holders of at least 50.1% of the outstanding shares of Series B Preferred Stock. In the event the Series B Preferred Stock automatically converts into common stock prior to the 36 month anniversary of the COD Effective Date, the holder on the date of such conversion shall also be entitled to receive those dividends which would have been payable after the conversion date, as if the shares of Series B Preferred Stock had remained unconverted and outstanding through the 36 month anniversary of the COD Effective Date. Such dividend amount shall be payable as set forth above in shares of common stock upon such automatic conversion.

Beneficial Conversion Feature. The Optional and Automatic conversion features do not contain a BCF as the effective conversion price for the Series B Preferred Stock at issuance was equal to the fair value of the common stock into which the preferred shares are convertible into.

Beneficial Ownership Limitation. The Company may not affect any optional or automatic conversion of the Series B Preferred Stock, or issue shares of common stock as dividends and a holder does not have the right to convert any portion of the Series B Preferred Stock to the extent that, after giving effect to such conversion such holder would beneficially own in excess of the Beneficial Ownership Limitation, or such holder, together with such holder's affiliates, and any persons acting as a group together with such holder or affiliates, would beneficially own in excess of the Beneficial Ownership Limitation. The "Beneficial Ownership Limitation" is 4.99% of the number of shares of the Company's common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon conversion of Series B Preferred Stock held by the applicable holder. A holder may, prior to issuance of the Series B Preferred Stock or, with 61 days prior notice to us, elect to increase or decrease the Beneficial Ownership Limitation; provided, however, that in no event may the Beneficial Ownership Limitation exceed 9.99%.

Liquidity Value and Dividends:

Dividends. Subject to the Beneficial Ownership Limitation described above, holders of the Series B Preferred Stock are entitled to receive dividends payable in the Company's common stock as follows: (i) a number of shares of common stock equal to 10% of the shares of common stock underlying the Series B Preferred Stock then held by such holder on the 12 month anniversary of the COD Effective Date, (ii) a number of shares of common stock equal to 15% of the shares of common stock underlying the Series B Preferred Stock then held by such holder on the 24-month anniversary of the COD Effective Date and (iii) a number of shares of common stock equal to 20% of the shares of common stock underlying the Series B Preferred Stock then held by such holder on the 36-month anniversary of the COD Effective Date. In the event a purchaser in this offering no longer holds Series B Preferred Stock as of the 12-month anniversary, the 24-month anniversary or the 36-month anniversary, such purchaser will not be entitled to receive any dividends on such anniversary date. Based on an accounting of the holders of record of Series B Preferred Stock on June 19, 2019 and 2020, the Company paid the 12-month anniversary dividend payments of 10% and 15%, respectively, totaling 946,000 shares and 1,365,600 shares, respectively, of common stock.

In the event a fundamental transaction is consummated prior to the automatic conversion of the Series B Preferred Stock, the dividends will be accelerated and paid to the extent not previously paid. In addition, holders of Series B Preferred Stock will be entitled to receive dividends equal, on an as-if-converted to shares of common stock basis, and in the same form as dividends actually paid on shares of the common stock when, as, and if such dividends are paid on shares of the common stock. Notwithstanding the foregoing, to the extent that a holder's right to participate in any dividend in shares of common stock to which such holder is entitled would result in such holder exceeding the Beneficial Ownership Limitation, then such holder shall not be entitled to participate in any such dividend to such extent and the portion of such shares that would cause such

holder to exceed the Beneficial Ownership Limitation shall be held in abeyance for the benefit of such holder until such time, if ever, as such holder's beneficial ownership thereof would not result in such holder exceeding the Beneficial Ownership Limitation.

Pursuant to its Certificate of Designation, the liquidation value of a share of Series B Preferred Stock is equal to the stated value of $1,000 per share (as adjusted for stock splits, stock dividends, combinations or other recapitalizations of the Series A Preferred Stock) plus any earned but unpaid dividends.

Warrants

The Company has issued two types of warrants: (i) investor warrants and (ii) placement agent warrants. All warrants are exercisable immediately upon issuance and have a five-year term. The warrants may be exercised at any time in whole or in part upon payment of the applicable exercise price until expiration. No fractional shares will be issued upon the exercise of the warrants. The exercise price and the number of shares purchasable upon the exercise of the investor warrants are subject to adjustment upon the occurrence of certain events, which include stock dividends, stock splits, combinations and reclassifications of the Company's capital stock or other similar changes to the equity structure of the Company.

For the 20 million investor warrants issued in 2015, the Company may call the warrants at any time the common stock trades above $3.00 for twenty (20) consecutive days following the effectiveness of the registration statement covering the resale of the shares of common stock underlying the warrants, provided that the warrants can only be called if such registration statement is current and remains effective at the time of the call and provided further that the Company can only call the investor warrants for redemption, if it also calls all other warrants for redemption on the terms described above. The Company did not call any warrants during the periods ended December 31, 2019 and 2020.

The placement agent warrants do not have a redemption feature. They may be exercised on a cashless basis at the holder's option.

The investor warrants and placement agent warrants are classified as equity instruments.

As of December 31, 2020, the Company had outstanding warrants to purchase an aggregate of 1,327,810 shares of common stock at exercise prices ranging from $0.50 to $0.75 per share. A summary of warrants outstanding as of December 31, 2020 and 2019 is presented below, all of which are fully vested (in thousands):

	Shares
Outstanding at December 31, 2018	5,799
Issued	-
Exercised	(402)
Tendered	-
Expired	-
Outstanding at December 31, 2019	5,397*
Issued	-
Exercised	(2,576)**
Tendered	-
Expired	(1,493)
Outstanding at December 31, 2020	1,328***

* Weighted average exercise price for outstanding warrants is $0.62.
** Converted into approximately 1,737 thousand shares of common stock.
*** Weighted average exercise price for outstanding warrants is $0.55.

Note 13 – Accumulated Other Comprehensive Income/(Loss)

The following table summarizes the changes in accumulated other comprehensive income/(loss) by components during the years ended December 31, 2020 and 2019 (in thousands):

	Net Unrealized (Losses)/Gains on Available-for-Sale Securities	Accumulated Other Comprehensive (Loss)/Gain
Balance, December 31, 2018	$ —	$ —
Net unrealized loss on securities available-for-sale	(1)	(1)
Reclassifications to net loss	—	—
Net current period other comprehensive loss	(1)	(1)
Balance, December 31, 2019	$ (1)	$ (1)
Net unrealized gain on securities available-for-sale	237	237
Reclassification of realized gain on securities available-for-sale to net loss	(8)	(8)
Net current period other comprehensive income	229	229
Balance, December 31, 2020	$ 228	$ 228

All components of accumulated other comprehensive income/(loss) are net of tax.

Note 14 – Stock-based Compensation

The Company's Amended and Restated 2013 Equity Compensation Plan (the "Plan") provides for the granting of incentive stock options, nonqualified stock options, restricted stock units, performance units, and stock purchase rights. Options under the Plan may be granted at prices not less than 100% of the fair value of the shareson the date of grant as determined by the Compensation Committee of the Board of Directors. The Compensation Committee determines the period over which the options become exercisable subject to certain restrictions as defined in the Plan, with the current outstanding options generally vesting over three or four years. The term of the options is no longer than ten years. As of December 31, 2020, the Company had 28,947,923 shares of common stock authorized for issuance under the Plan.

With the approval of the Board of Directors and a majority of shareholders, effective May 8, 2014, the Plan was amended and restated. The amendment provides for an automatic increase in the number of shares of common stock available for issuance under the Plan each January (with Board approval), commencing January 1, 2015 in an amount up to four percent (4%) of the total number of shares of common stock outstanding on the preceding December 31st.

The Company recognized stock-based compensation expense (options and restricted share grants) in its consolidated statements of operations as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Research and Development	$ 1,897	$ 973
General and Administrative	2,668	2,012
Total	$ 4,565	$ 2,985

The following table contains information about the Company's stock plan at December 31, 2020:

	Awards Reserved for Issuance	Awards Issued & Exercised	Awards Available for Grant
2013 Equity Compensation Plan (in thousands)	28,948*	25,928**	3,020

* Increased by 6,526 thousand on January 1, 2020, representing 4% of the total number of shares of common stock outstanding on December 31, 2019.
** Includes both stock grants and option grants

The following table summarizes the Company' stock option activity and related information for the period from January 1, 2019 to December 31, 2020 (options in thousands):

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Term in Years
Outstanding at January 1, 2019	13,457	$ 1.13	6.2
Granted	4,539	$ 1.05	
Exercised	(73)	0.42	
Forfeited	(334)	$ 1.00	
Cancelled	-	-	
Expired	(60)	$ 2.19	
Outstanding at December 31, 2019	17,529	$ 1.11	6.2
Granted	6,501	$ 1.59	
Exercised *	(826)	$ 0.74	
Forfeited	(72)	$ 1.11	
Cancelled	-	-	
Expired	(581)	$ 1.25	
Outstanding at December 31, 2020	22,551	$ 1.26	6.9

* Resulted in the issuance of approximately 782 thousand shares of common stock due to certain cashless exercises.

The following table summarizes outstanding options at December 31, 2020, by their exercise price (options in thousands):

Range of Exercise Prices	Number Outstanding	Weighted Average Exercise Price Per Share
$0.41 - $0.69	2,682	$ 0.48
$0.74 - $1.12	12,326	$ 0.92
$1.24 - $1.61	2,788	$ 1.33
$2.27 - $3.32	4,755	$ 2.55
	22,551	$ 1.26

As of December 31, 2020, the number of vested shares underlying outstanding options was 13,413,955 at a weighted average exercise price of $1.15. The aggregate intrinsic value of in-the-money options outstanding as of December 31, 2020 was $8.0 million. The aggregate intrinsic value is calculated as the difference between the Company's closing stock price of $1.36 on December 31, 2020, and the exercise price of options, multiplied by the number of options. As of December 31, 2020, there was approximately $8.8 million of total unrecognized share-based compensation. Such costs are expected to be recognized over a weighted average period of approximately 2.6 years.

All outstanding options expire ten years from date of grant. Options granted to employees prior to 2018 vest in equal monthly installments over three years. Beginning in 2018, options granted to employees vest over four years, with 25% of the shares vesting on the first annual anniversary of grant and the remaining shares vesting in 36 equal monthly installments over the following 3 years. A portion of options granted to consultants vests over four years, with the remaining vesting being based upon the achievement of certain performance milestones, which are tied to either financing or drug development initiatives.

During the years ended December 31, 2020 and 2019, the Company granted restricted stock awards for 379,385 and 441,005 shares of common stock, respectively. These awards are typically granted to members of the Board of Directors as payment in lieu of cash fees or as payment to a vendor pursuant to a consulting agreement. The Company values restricted stock awards at the fair market value on the date of grant. The Company recorded the value of these restricted awards as general and administrative expense of approximately $291.9 thousand and $360.1 thousand in the consolidated statement of operations for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, there was $68.5 thousand of total unrecognized compensation costs related to 100,000 non-vested restricted stock grants which are expected to be recognized over a weighted-average period of 0.8 years.

The Company recognizes compensation expense for stock option awards and restricted stock awards on a straight-line basis over the applicable service period of the award. The service period is generally the vesting period, with the exception of awards granted subject to a vendor's consulting agreement, whereby the award vesting period and the service period defined pursuant to the terms of the consulting agreement may be different. Beginning January 1, 2020, stock options issued to consultants are recorded at fair value on the date of grant and the award is recognized as an expense on a straight-line basis over the requisite service period. The following weighted-average assumptions were used to calculate share-based compensation for the comparative periods presented:

	For the Year Ended December 31,	
	2020	2019
Volatility	100.5% - 107.4%	106.1% - 111.3%

Risk-free interest rate	0.34% - 1.74%	1.59% - 2.65%
Dividend yield	0.0%	0.0%
Expected life	6.0 years	6.0 years

The Company does not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior. Hence, the Company uses the "simplified method" described in Staff Accounting Bulletin (SAB) 107 to estimated the expected term of share option grants.

The expected stock price volatility assumption is based the Company's historical stock price volatility.

Note 15 – Subsequent Events

During January 2021, the Company sold 3,023,147 shares of its common stock under its ATM Sales Agreement with BTIG, LLC, generating gross proceeds of approximately $5.8 million and net proceeds of approximately $5.6 million.

Exhibit 4.6

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

The following is a description of our common stock and preferred stock as set forth in our certificate of incorporation and bylaws, each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K to which this Exhibit 4.6 is a part. This summary does not purport to be complete and is qualified in its entirety by the full text of our aforementioned certificate of incorporation and bylaws and by applicable law.

Our authorized capital stock consists of 500,000,000 shares of common stock, par value $0.0001 per share and 10,000,000 shares of Preferred Stock, par value $0.0001 per share.

The additional shares of our authorized stock available for issuance might be issued at times and under circumstances so as to have a dilutive effect on earnings per share and on the equity ownership of the holders of our common stock. The ability of our board of directors to issue additional shares of stock could enhance the board's ability to negotiate on behalf of the stockholders in a takeover situation but could also be used by the board to make a change-in-control more difficult, thereby denying stockholders the potential to sell their shares at a premium and entrenching current management. The following description is a summary of the material provisions of our capital stock. You should refer to our amended and restated certificate of incorporation and by-laws, both of which are on file with the SEC as exhibits to previous SEC filings, for additional information. The summary below is qualified by provisions of applicable law.

Common Stock

Voting. The holders of our common stock are entitled to one vote for each share held of record on all matters on which the holders are entitled to vote (or consent to).

Dividends. The holders of our common stock are entitled to receive, ratably, dividends only if, when and as declared by our board of directors out of funds legally available therefor and after provision is made for each class of capital stock having preference over the common stock (including the common stock).

Liquidation Rights. In the event of our liquidation, dissolution or winding-up, the holders of our common stock are entitled to share, ratably, in all assets remaining available for distribution after payment of all liabilities and after provision is made for each class of capital stock having preference over the common stock (including the common stock).

Conversion Rights. The holders of our common stock have no conversion rights.

Preemptive and Similar Rights. The holders of our common stock have no preemptive or similar rights.

Redemption/Put Rights. There are no redemption or sinking fund provisions applicable to the common stock. All of the outstanding shares of our common stock are fully-paid and nonassessable.

Transfer Agent and Registrar. The transfer agent and registrar for our common stock is VStock Transfer, LLC.

Preferred Stock

We are authorized to issue up to 10,000,000 shares of preferred stock, par value $0.0001 per share, (of which 1,600,000 shares have been designated as Series A Preferred Stock) with such designations, rights, and preferences as may be determined from time to time by our board of directors. Accordingly, our board of directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting, or other rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock could have the effect of restricting dividends on our common stock, diluting the voting power of our common stock, impairing the liquidation rights of our common stock, or delaying or preventing a change in control of our company, all without further action by our stockholders.

Our board of directors has the authority, within the limitations and restrictions prescribed by law and without stockholder approval, to provide by resolution for the issuance of shares of preferred stock, and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preference and the number of shares constituting any series of the designation of such series, by delivering an appropriate certificate of amendment to our amended and restated certificate of incorporation to the Delaware Secretary of State pursuant to the Delaware General Corporation Law (the "DGCL"). The issuance of preferred stock could have the effect of decreasing the market price of the common stock, impeding or delaying a possible takeover and adversely affecting the voting and other rights of the holders of our common stock.

If we offer a specific series of preferred stock under this prospectus, we will describe the terms of the preferred stock in the prospectus supplement for such offering and will file a copy of the certificate establishing the terms of the preferred stock with the SEC. To the extent required, this description will include:

- the title and stated value;
- the number of shares offered, the liquidation preference per share and the purchase price;
- the dividend rate(s), period(s) and/or payment date(s), or method(s) of calculation for such dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction and remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption, if applicable;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price (or how it will be calculated) and conversion period;
- whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price (or how it will be calculated) and exchange period;
- voting rights, if any, of the preferred stock;
- a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of the affairs of Matinas; and
- any material limitations on issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of Matinas.

Transfer Agent and Registrar for Preferred Stock. The transfer agent and registrar for any series or class of preferred stock will be set forth in each applicable prospectus supplement.

Series A Preferred Stock

Our board of directors created out of the authorized and unissued shares of our preferred stock, a series of preferred stock comprised of 1,600,000 shares of Series A Preferred

Stock. All shares of Series A Preferred Stock have been automatically converted pursuant to the terms of the certificate of designation.

Series B Preferred Stock

Our board of directors created out of the authorized and unissued shares of our preferred stock, a series of preferred stock comprised of 15,000 shares of Series B Preferred Stock. Each share of Series B Preferred have a stated value of $1,000 per share.

Rank. The Series B Preferred rank

- junior to our Series A Preferred Stock and any class or series of our capital stock hereafter created specifically ranking by its terms senior to the Series B Preferred;
- senior to all of our common stock;

- senior to any class or series of our capital stock hereafter created specifically ranking by its terms junior to the Series B Preferred; and
- on a parity with any class or series of our capital stock hereafter created specifically ranking by its terms on a parity with the Series B Preferred.

in each case, as to distributions of assets upon our liquidation, dissolution or winding up whether voluntarily or involuntarily.

Dividends. Holders of the Series B Preferred are entitled to receive dividends payable as follows: (i) a number of shares of common stock equal to 10% of the shares of common stock underlying the Series B Preferred then held by such holder on the 12 month anniversary of the COD Effective Date, (ii) a number of shares of common stock equal to 15% of the shares of common stock underlying the Series B Preferred then held by such holder on the 24-month anniversary of the COD Effective Date and (iii) a number of shares of common stock equal to 20% of the shares of common stock underlying the Series B Preferred then held by such holder on the 36-month anniversary of the COD Effective Date. In the event a purchaser in this offering no longer holds Series B Preferred as of the 12-month anniversary, the 24-month anniversary or the 36 month anniversary, such purchaser will not be entitled to receive any dividends on such anniversary date.

Optional Conversion. Each share of Series B Preferred is convertible into shares of our common stock at any time at the option of the holder at a conversion price $0.50 per share (subject to adjustment for reverse splits, stock combinations and similar changes as provided in the certificate of designation). Holders of Series B Preferred are prohibited from converting Series B Preferred into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own more than 4.99% (or upon the election by a holder prior to the issuance of any shares of Series B Preferred, 9.99%) of the total number of shares of our common stock then issued and outstanding. Dividends will not accrue and will not be paid following optional conversion.

Automatic Conversion. Each share of our Series B Preferred shall automatically convert into 2,000 shares of our common stock at a conversion price of $0.50 per share upon the earlier of (i) the first FDA approval of one of our product candidates, (ii) the 36-month anniversary of the COD Effective Date or (iii) the consent to conversion by holders of at least 50.1% of the outstanding shares of Series B Preferred. In the event the Series B Preferred automatically converts into common stock prior to the 36 month anniversary of the COD Effective Date, the holder on the date of such conversion shall also be entitled to receive those dividends which would have been payable after the conversion date, as if the shares of Series B Preferred had remained unconverted and outstanding through the 36 month anniversary of the COD Effective Date. Such dividend amount shall be payable as set forth above in shares of common stock upon such automatic conversion.

Liquidation Preference. In the event of a liquidation, dissolution or winding-up of our company, whether voluntary or involuntary, the proceeds and/or assets of our company remaining after giving effect to such transaction, and the payment of all of our debts and liabilities will be distributed first to the holders of our Series A Preferred Stock and thereafter to the holders of Series B Preferred and then to stockholders of common stock (including the holders of our Series A Preferred Stock and Series B Preferred on an "as converted" basis) on a pro rata basis.

Voting Rights. Except as provided in the Certificate of Designation of the Series B Preferred or as otherwise required by law, the holders of Series B Preferred will have no voting rights. However, we may not, without the consent of holders of a majority of the outstanding shares of Series B Preferred, alter or change adversely the powers, preferences or rights given to the Series B Preferred, increase the number of authorized shares of Series B Preferred, or enter into any agreement with respect to the foregoing.

Redemption. We will be not obligated to redeem or repurchase any shares of Series B Preferred. Shares of Series B Preferred will not otherwise be entitled to any redemption rights or mandatory sinking fund or analogous fund provisions.

Transfer Agent, Registrar and Dividend Disbursing Agent. The transfer agent, registrar and dividend disbursing agent for our Series B preferred stock is VStock Transfer, LLC.

Anti-takeover Effects of Delaware Law and of our Amended and Restated Certificate of Incorporation

The following paragraphs summarize certain provisions of the DGCL and our amended and restated certificate of incorporation that may have the effect of discouraging an acquisition of Matinas. The summary does not purport to be complete and is subject to and qualified in its entirety by reference to the DGCL and our amended and restated certificate of incorporation and by-laws, copies of which are on file with the SEC. Please refer to "Additional Information" below for directions on obtaining these documents.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Certificate of Incorporation and Bylaws

Our certificate of incorporation and bylaws contain provisions that could have the effect of discouraging potential acquisition proposals or tender offers or delaying or preventing a change of control of our company. These provisions are as follows:

- they provide that special meetings of stockholders may be called only by the board of directors, President or our Chairman of the board of directors, or at the request in writing by stockholders of record owning at least fifty (50%) percent of the issued and outstanding voting shares of common stock;
- they do not include a provision for cumulative voting in the election of directors. Under cumulative voting, a minority stockholder holding a sufficient number of shares may be able to ensure the election of one or more directors. The absence of cumulative voting may have the effect of limiting the ability of minority stockholders to effect changes in our board of directors; and
- they allow us to issue "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval.

Potential Effects of Authorized but Unissued Stock

We have shares of common stock and preferred stock available for future issuance without stockholder approval. We may utilize these additional shares for a variety of corporate purposes, including future public offerings to raise additional capital, to facilitate corporate acquisitions or payment as a dividend on the capital stock.

The existence of unissued and unreserved common stock and preferred stock may enable our board of directors to issue shares to persons friendly to current management or to issue preferred stock with terms that could render more difficult or discourage a third-party attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise, thereby protecting the continuity of our management. In addition, the board of directors has the discretion to determine designations, rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences of each series of preferred stock, all to the fullest extent permissible under the DGCL and subject to any limitations set forth in our amended and restated certificate of incorporation. The purpose of authorizing the board of directors to issue preferred stock and to determine the rights and preferences applicable to such preferred stock is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing desirable flexibility in connection with possible financings, acquisitions and other corporate purposes, could have the effect of making it more difficult for a third-party to acquire, or could discourage a third-party from acquiring, a majority of our outstanding voting stock.

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS NOT MATERIAL AND WOULD LIKELY CAUSE COMPETITIVE HARM TO THE REGISTRANT IF PUBLICLY DISCLOSED. THE OMISSIONS HAVE BEEN INDICATED BY "[***]."

THERAPEUTIC DEVELOPMENT AWARD AGREEMENT

November 17, 2020

Development Program:	MAT2501 for the Treatment of NTM Infections in Cystic Fibrosis Patients
Awardee:	Matinas BioPharma Nanotechnologies, Inc. (the "Awardee")
Award Number:	MATINAS20W0
Award Amount:	$4,234,249, consisting of $484,249 previously advanced and up to an additional $3,750,000 in accordance with the Payment Schedule attached hereto as Exhibit B

1. Award. The Cystic Fibrosis Foundation, a Delaware corporation ("**CFF**"), is issuing this award (this "**Award**") to the Awardee for the Development Program named above and described in Exhibit A. CFF will fund the Development Program up to the New Award Amount (as defined below), and Awardee will pay all of the remaining costs in excess of the Award required to complete the Development Program and to further develop and commercialize the Product (as described below). $359,249 of the Award Amount was previously disbursed to the Awardee pursuant to the Letter Agreement, dated as of November 16, 2016, by and between CFF and the Awardee, and $125,000 of the Award Amount was previously disbursed to the Awardee pursuant to the Letter Agreement, dated as of February 12, 2020, by and between CFF and the Awardee, which amounts are included in the Award Amount hereunder pursuant to Section 2 of each such Letter Agreement. CFF will advance up to an additional $3,750,000 (the "**New Award Amount**") to fund the Development Program. Each party's rights and obligations hereunder will commence as of the date written above (the "**Effective Date**"). This Award is in furtherance of CFF's charitable mission to cure and mitigate the effects of cystic fibrosis. CFF has determined that without the Award, the Development Program may not occur or may be substantially delayed. The Award is subject to the terms, conditions and policies of this Agreement ("**Agreement**").

2. Disbursement of Award; Use of Award; Return of Award. The New Award Amount will be disbursed to the Awardee in accordance with the Payment Schedule set forth in Exhibit B. The Awardee hereby covenants and agrees to use the New Award Amount solely to fund the Development Program. Any portion of the New Award Amount paid to the Awardee and not expended on the Development Program must be returned to CFF promptly upon the Awardee's determination that such funds will not be expended on the Development Program, and in any event within thirty (30) days following completion or termination of the Development Program. Upon such return, the amounts of such returned funds will not be included as part of the Actual Award for purposes of calculating any royalties or other amounts owed by the Awardee to CFF pursuant to Section 3.

3. Royalties. In consideration of the Award and CFF's license of CFF Know-How (as defined below), the Awardee agrees to pay royalties to CFF as follows:

(a) The Awardee shall pay a one-time royalty (the "Royalty") to CFF in an amount equal to the Royalty Cap if a Product (as defined below) resulting from the Development Program is approved for commercial sale for human therapeutic use, payable in three (3) equal installments: the first within ninety (90) days after the first commercial sale of the Product for human therapeutic use in the Field (the "First Sale"); the second within ninety (90) days of the first (1st) anniversary of the First Sale; and the third within ninety (90) days of the second (2nd) anniversary of the First Sale; provided however in no event shall the Royalty payable for any particular installment be greater than 25% of Net Sales of the Product (the "Royalty Payment Cap') during the twelve (12) month period ending on the date of such payment. If the amount of the Royalty due for any applicable period is greater than the Royalty Payment Cap, then in such instance the difference between the Royalty due and the Royalty Payment Cap shall be carried over to next payment date until such time that the Royalty is paid in full. If the Royalty is not paid in full by ninety (90) days following the second anniversary of the First Sale, the term of the Royalty repayment shall be automatically extended for additional twelve-month periods until the Royalty has been paid in full. In addition to the extent CFF receives any payments pursuant to 3(b) below, each Royalty installment payment shall be reduced pro-rata after crediting of the amounts paid pursuant to Section 3(b).

(b) In the event of a License (as defined below) or a Change of Control Transaction (as defined below), subject to Section 3(d), the Awardee shall pay to CFF an amount equal to [***] percent ([***]%) of all License Revenue (as defined below) or [***] percent ([***]%) of all COC Consideration (as defined below), respectively. Such amount shall be payable within ninety (90) days after the Awardee's (or, if applicable, the Awardee's Affiliates' or equity holders') receipt of any such amount.

(c) If Net Sales exceed $[***] million, the Awardee shall pay a one-time royalty to CFF in an amount equal to one (1) times the Actual Award within ninety (90) days of the end of the first calendar year in which such total Net Sales were achieved. If Net Sales exceed $[***] million, the Awardee shall pay a one-time royalty to CFF in an amount equal to one (1) times the Actual Award within ninety (90) days of the end of the first calendar year in which such total Net Sales were achieved.

(d) Notwithstanding anything to the contrary, the total, aggregate, combined amount payable to CFF under Sections 3(a) and 3(b) shall not in any event exceed the Royalty Cap.

4. Commercially Reasonable Efforts. The Awardee shall use Commercially Reasonable Efforts (as defined below) to conduct the Development Program during the term of this Agreement. After the Development Program is completed, the Awardee (or any licensee, sublicensee, assignee or successor, as applicable) shall exercise Commercially Reasonable Efforts to continue to develop the Product in the Field.

5. Reports and Notices.

(a) During the Development Program, the Awardee shall provide CFF and the PAG (as defined below) with a reasonably detailed, written report within forty five (45) days after the close of each calendar quarter during the Development Program summarizing progress toward achieving the goals of the Development Program.

(b) The Awardee shall provide a Milestone Report within thirty (30) days following the completion of each milestone, as set forth inExhibit B.

(c) The Awardee shall prepare and deliver to CFF a closing report within thirty (30) days after the completion of the Development Program and receipt by Awardee of the final clinical study report related to the Development Program.

(d) After the completion of the Development Program, the Awardee shall prepare and deliver a report to CFF annually, on or before each anniversary of the Effective

Date, detailing the progress of its research and development activities regarding the Product in the Field, until the earlier of (i) the First Sale, (ii) all research efforts related to the Product in the Field are abandoned by the Awardee, and (iii) the Interruption License Effective Date (as defined below).

(e) The Awardee shall annually provide CFF a copy of its auditor's most recent management letter within thirty (30) days of issuance of such letter.

(f) The Awardee shall provide CFF with prompt notice of the closing of a Change of Control Transaction, and of any material adverse event which would reasonably be expected to adversely impact the Development Program.

(g) Commencing upon the First Sale and ending upon payment of all amounts due under Section 3(c), within forty five (45) days after the end of each year, the Awardee shall furnish to CFF a written sales report covering the prior year setting forth the Net Sales during such year.

6. Program Advisory Group.

(a) The Awardee and CFF shall form a Program Advisory Group ("**PAG**"). The purpose of the PAG is to ensure that the Award is used solely in furtherance of CFF's tax-exempt mission, to facilitate communications between the Parties and to make recommendations with respect to the Development Plan. The PAG shall review progress of the Development Program; determine, discuss and propose amendments to the Development Program or the Budget; determine whether payment milestones have been achieved; and consider and provide non-binding recommendations on other issues raised by either party relating to the Development Program; provided, however, that no change to the Development Program shall be made without the written agreement of both parties. All decisions of the PAG shall be made within thirty (30) days after the date on which a party first presents a particular matter for consideration by the PAG. In the event that the PAG cannot make a decision with respect to any matter, such matter shall be escalated to the CEO of Awardee and the CEO of CFF, or their respective designees, (collectively, the "Senior Executives") to determine such matter within thirty (30) days after the date on which such matter has been referred to such Senior Executives, which determination shall be binding on the parties. In the event the Senior Executives are unable to reach agreement, then the CEO of Awardee shall have the right to make the final decision on such matter.

(b) The PAG shall consist of two (2) individuals appointed by the Awardee and two (2) individuals appointed by CFF. One of such individuals from the Awardee and CFF, respectively, shall be the principal liaison to the Development Program. A party may replace any PAG member appointed by it and designate a new individual to serve on the PAG upon written notice to the other party. The PAG shall meet at least on a quarterly basis.

(c) The PAG shall terminate and cease to exist on the earlier of the completion of the Development Program or termination or expiration of this Agreement.

(d) Each party shall be responsible for its own expenses in connection with attending meetings of and participating in the PAG.

7. Interruption License.

(a) **Grant of License**. Subject to the terms and conditions of this Agreement, and effective as of the Interruption License Effective Date (as defined below), the Awardee hereby grants to CFF (i) an exclusive (even as to the Awardee), worldwide, perpetual, sublicensable license under the Development Program Technology (as defined below) solely to the extent necessary to manufacture, have manufactured, license, use, sell, offer to sell, and support the Product in the Field and (ii) a non-exclusive worldwide License under the Awardee Background IP to the extent necessary or beneficial to manufacture, have manufactured, license, use, sell, offer to sell, and support the Product in the Field. For the avoidance of doubt. Awardee shall retain all rights to Development Program Technology for use outside the Field and any other intellectual property owned or controlled by Awardee including the Awardee Background IP both inside and outside the Field.

(b) **Interruption Notice; Awardee Election**. Awardee shall notify CFF if an Interruption (as defined below) has occurred. If Awardee provides such notice, or if CFF otherwise believes that an Interruption has occurred, CFF will provide notice (the "**Interruption Notice**") to Awardee. The Awardee shall elect, within thirty (30) days of the Interruption Notice, one of the following options by notice to CFF:

(i) The Awardee shall reasonably demonstrate, in the form of a written progress report, that an Interruption has not occurred, or that the Awardee, an Affiliate thereof, or a licensee or sublicensee of either of the foregoing is exercising Commercially Reasonable Efforts to develop or commercialize a Product in the Field;

(ii) The Awardee shall provide CFF with notice within such thirty (30) day period that the Awardee, an Affiliate thereof, or a licensee or sublicensee of either of the foregoing, has plans to initiate or resume Commercially Reasonable Efforts to develop or commercialize a Product in the Field and initiates or resumes such Commercially Reasonable Efforts within the sixty (60) day period following such notice; provided that Awardee may select this option only once; or

(iii) The Interruption License shall become effective, as set forth below.; or

If the Awardee has not elected (i) or (ii) above within thirty (30) days of the Interruption Notice, or if it has elected (i) or (ii) above but has not satisfied the requirements thereof within the time period required, the Awardee shall be deemed to have made the election specified in (iii) above. The failure of the Product due to safety issues or lack of efficacy in the Field or regulatory restrictions shall not constitute an Interruption. In addition, the Interruption License shall automatically terminate and be of no further force or effect following payment in full by Awardee or any of its sublicensees or assigns of the Royalty under Section 3(a).

(c) **Effectiveness of License**. If the Awardee has made or is deemed to have made the election specified in (iii) above, the Interruption License shall be effective upon such election (or deemed election) (such date, the "**Interruption License Effective Date**").

(d) **Materials and Data**. The Awardee shall deliver to CFF, within thirty (30) days of the Interruption License Effective Date, a copy of all materials and data in its possession or control generated in the performance of the Development Program and/or constituting the Development Program Technology to the extent required by CFF to make, use or sell the Product in the Field.

(e) **Assignment of Rights**. In the event that the Awardee assigns all of or certain of its rights and obligations to develop and commercialize a Product at any time to a third party, such third party shall be subject to the obligations of the Interruption License.

(f) **License as Intellectual Property**. The Interruption License shall be deemed to constitute intellectual property as defined in Section 365(n) of the U.S. Bankruptcy Code. the Awardee agrees that CFF, as a licensee of such rights, shall retain and may exercise all of its rights and elections under the U.S. Bankruptcy Code; provided, however, that nothing in this Agreement shall be deemed to constitute a present exercise of such rights and elections.

(g) **Third-Party Technology**. To the extent Development Program Technology or applicable Awardee Background IP includes any intellectual property in-licensed from a third party, the Awardee will inform CFF in writing, and CFF will elect by written notice to the Awardee either to (i) obtain a sublicense to such intellectual property from the Awardee, in which case CFF shall assume the Awardee's obligations to such third party under the in-license, or (ii) exclude such intellectual property from the Interruption License.

8. Indemnification.

(a) The Awardee shall indemnify, defend and hold harmless CFF, its Affiliates, and their respective directors, officers, employees, consultants, committee members, volunteers, agents and representatives and their respective successors, heirs and assigns (each, an "**CFF Indemnitee**") from and against any and all claims, suits and demands of third parties and losses, liabilities, damages for personal injury, property damage or otherwise, costs, penalties, fines and expenses (including court costs and the reasonable fees of attorneys and other professionals) ("**Liabilities**") payable to such third parties arising out of, resulting therefrom and relating to any such third party claims, suits and/or demands ("**Third Party Claims**") resulting from:

(i) the conduct of the Development Program by the Awardee or its Affiliates or their respective directors, officers, employees, consultants, agents, representatives, licensees, sublicensees, subcontractors and/or investigators (each, an "**Awardee Party**") under this Agreement and/or pursuant to one or more agreements between the Awardee and any the Awardee Party, or any actual or alleged violation of law resulting therefrom;

(ii) the Awardee's or its Affiliates' development, manufacture, or commercialization of any Product;

(iii) any claim of infringement or misappropriation with respect to the conduct of the Development Program by or on behalf of the Awardee, its Affiliates, or the Awardee or its Affiliate's third party licensees or sublicenses, or with respect to the manufacture, use, sale, or import of any Product by any such parties other than any such claim to the extent deriving from the use of CFF Know How; and

(iv) any tort claims of personal injury (including death) relating to or arising out of any such injury sustained as the result of, or in connection with, the conduct of the Development Program by or on behalf of the Awardee, its Affiliates, or the Awardee or its Affiliate's third party licensees or sublicenses, or with respect to the manufacture, use, sale, or import of any Product by any such parties;

(v) in each case except to the extent the claim, suit, demand, liability, damage, or loss results from the gross negligence or willful misconduct of a CFF Indemnitee.

(b) CFF shall indemnify, defend and hold harmless the Awardee, its Affiliates and their respective directors, officers, employees, consultants, agents and representatives and their respective successors, heirs and assigns (the "**Awardee Indemnitees**") from and against any and all Liabilities payable to such third parties arising out of, resulting from, or relating to any Third Party Claims resulting from: (i) exercise of any rights under the Interruption License by or on behalf of CFF, any successor in interest thereto, or any licensee or sublicensee of any of the foregoing (which shall in any event include any claim of patent infringement or trade secret misappropriation resulting from the manufacture, use, sale, development, commercialization, or import of any Product or practice of any the Development Program Technology) or (ii) CFF's gross negligence, intentional misconduct, or failure to comply with any applicable law, rule, or regulation with respect thereto, in each case except to the extent the claim, suit, demand, liability, damage or loss results from the gross negligence or willful misconduct of an Awardee Indemnitee.

(c) A party entitled to indemnification under this Section 8 (the "**Indemnified Party**") will promptly notify the other Party (the "**Indemnifying Party**") of any claims, suits, demands, losses, liabilities, damages costs, penalties, fines, or expenses subject to indemnification under this Section 8 of which it is made aware. The Indemnified Party will cooperate, and exert efforts to cause other Indemnified Parties to cooperate, in assisting the Indemnifying Party in presenting a defense, if requested to do so. The Indemnifying Party shall have sole control to select defense counsel, direct the defense of any such complaint or claim, and the right to settle claims at the Indemnifying Party's sole expense, provided that any such settlement does not incur non-indemnified liability for or admit fault by any Indemnified Party. In the event a claim or action is or may be asserted, the Indemnified Party shall have the right to select and to obtain representation by separate legal counsel. If the Indemnified Party exercises such right, all costs and expenses incurred for such separate counsel shall be borne by the Indemnified Party. No Indemnified Party shall settle or enter into any voluntary disposition of any matter subject to indemnification under this Section 8 without the prior written consent of the Indemnifying Party, such consent not to be unreasonably withheld.

9. Insurance. The Awardee shall maintain at its own expense, with a reputable insurance carrier, coverage for the Awardee, its Affiliates, and their respective employees written on a per occurrence basis commensurate with a reasonable assessment of the risks associated with the research and development efforts being conducted by the Awardee, the following policies: commercial general liability insurance, including contractual liability as respects this Agreement for bodily injury and property damage and, no later than the first administration of a Product to a human subject, products liability and clinical trials liability.

Maintenance of such insurance coverage will not relieve the Awardee of any responsibility under this Agreement for damage in excess of insurance limits or otherwise. On or prior to the Effective Date of this Agreement, the Awardee shall provide CFF with an insurance certificate from the insurer(s), broker(s) or agent(s) evidencing the applicable insurance coverage. At CFF's request, CFF may review the Awardee's insurance coverage with relevant Awardee personnel no more than one time per year.

10. Intellectual Property Rights.

(a) All inventions, data, know-how, information, results, analyses, and other intellectual property rights resulting from the Development Program shall, as between the parties, be owned by the Awardee and the preparation, filing and maintenance of all patents resulting from the Development Program shall, as between the parties, be the sole responsibility, and under the sole control, of the Awardee. CFF hereby assigns and transfers to the Awardee all of CFF's right, title, and interest in and to all inventions and other intellectual property resulting from the Development Program, CFF's access to, or knowledge or use of, any Development Program Technology, Product, or confidential or proprietary information of the Awardee, and all intellectual property rights related to any of the foregoing, free and clear of all liens, claims, and encumbrances. CFF agrees to take, and cause all of its employees, agents, and other representatives to take, any and all actions, and execute any and all documents, reasonably requested by the Awardee as necessary to effect the foregoing.

(b) To the extent CFF provides or makes available any information, expertise, know-how or other intellectual property related to cystic fibrosis or the treatment, prevention, or cure thereof ("**CFF Know-How**") to the Awardee, CFF hereby grants to the Awardee a non-exclusive, perpetual, transferable, sublicensable (through multiple tiers), worldwide right and license under all of CFF's rights in such CFF Know-How to research, develop, commercialize, make, use, sell, offer for sale, import and otherwise exploit the Product in the Field.

11. Confidentiality. All information made available hereunder will be governed by that certain Nondisclosure Agreement, dated as of August 22, 2019, by and between the Parties.

12. Audits. At the request of CFF, from time to time, the Awardee shall permit CFF, upon reasonable notice, to audit and examine such books and records of the Awardee as may be necessary for verifying the Awardee's expenditures of the Award Amount and the payment of royalties, if any, but no more frequently than once every calendar year.

13. Term and Termination. The term of this Agreement shall commence on the Effective Date and expire on the earlier of the date on which the Awardee has paid CFF the Royalty and all of the royalty payments set forth in Section 3, or the Interruption License Effective Date. Either party may terminate this Agreement for cause, without prejudice to any other remedies available, by providing the other party with written notice of such cause and intent to terminate; provided, however, that the other party shall have thirty (30) days following the receipt of written notice to cure such cause and, in the event of such cure, such termination shall not be effective. For this Section 11, "cause" shall mean (i) a party's material breach of its covenants or obligations under this Agreement, (ii) a bankruptcy or similar filing by a party or a proceeding under the applicable

bankruptcy laws or under any dissolution or liquidation law or statute now or hereafter in effect and filed against such party or all of substantially all of its assets if such filing is not dismissed within sixty (60) days after the date of its filing, or (iii) the Awardee's material failure to achieve any milestone described in Exhibit A or B within ninety (90) days after its anticipated achievement date; provided however that in the event there is a regulatory, scientific or other technical delay in achieving such milestone that is beyond the reasonable control of Awardee (a "Tolling Event"), Awardee provides CFF with notice of any such anticipated delay as soon as reasonably practicable after becoming aware that such a delay is likely, and Awardee uses its Commercially Reasonable Efforts to overcome such delay during its pendency, Awardee shall not be deemed to have failed to meet a required milestone during the pendency of a Tolling Event. The following provisions shall survive the termination of this Agreement: Sections 3, 7, 8, 9, 10, 11, 12, 13 and 14.

14. Miscellaneous.

(a) **Governing Law**. This Agreement shall be governed by and construed in accordance with the internal laws of the State of Maryland.

(b) **Dispute Resolution**.

(i) In the event of any dispute, claim or controversy arising out of, relating to or in any way connected to the interpretation of any provision of this Agreement, the performance of either party under this Agreement or any other matter under this Agreement, including any action in tort, contract or otherwise, at equity or law (a "**Dispute**"), either party may at any time provide the other party written notice specifying the terms of such Dispute in reasonable detail. As soon as practicable after receipt of such notice, an officer of each party shall meet at a mutually agreed upon time and location to engage in good faith discussions for the purpose of resolving such Dispute. If the Dispute is not resolved within thirty (30) days of such notice, either party may institute arbitration in accordance with (ii) below.

(ii) In the event any Dispute is not resolved in accordance with Section 12(b)(i), such Dispute shall be resolved by final and binding arbitration. Whenever a party decides to institute arbitration proceedings, it shall give written notice to that effect to the other party. Arbitration shall be held in New York, New York, according to the then-current commercial arbitration rules of the Center for Public Resources ("CPR"), except to the extent such rules are inconsistent with this subparagraph. The arbitration will be conducted by one (1) independent, neutral arbitrator who shall be mutually acceptable to both parties, such acceptance not to be unreasonably withheld, and who shall be appointed in accordance with CPR rules. If the parties are unable to mutually agree on such an arbitrator, then the arbitrator shall be appointed in accordance with CPR rules. Any arbitrator chosen hereunder shall have educational training and industry experience sufficient to demonstrate a reasonable level of relevant scientific, financial, medical and industry knowledge. Within twenty (20) days of the selection of the arbitrator, each party shall submit to the arbitrator a proposed resolution of the Dispute that is the subject of the arbitration (the "Proposals"). The arbitrator shall thereafter select one of the Proposals so submitted as the resolution of the Dispute, but may not alter the terms of either Proposal and may not resolve the Dispute in a manner other than by selection of one of the submitted Proposals. If a party fails to submit a Proposal, the arbitrator shall select the Proposal of the other party as the resolution of the Dispute. The arbitrator shall agree to render its opinion within thirty (30) days of the final arbitration hearing. No arbitrator shall have the power to award punitive damages regardless of whether any such damages are contained in a Proposal, and such award is expressly prohibited. The proceedings and decisions of the arbitrator shall be confidential, final and binding on all of the parties. Judgment on the award so rendered may be entered in any court having jurisdiction thereof. The parties shall share the costs of arbitration according to the decision of the arbitrator. Nothing in this subparagraph will preclude either party from seeking equitable or injunctive relief, or interim or provisional relief, from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction, or any other form of permanent or interim equitable or injunctive relief, concerning a dispute either prior to or during any arbitration.

(c) **Counterparts**. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same Agreement. Facsimile and other electronically scanned signatures shall have the same effect as their originals.

(d) **Notices**. All communications between the parties with respect to any of the provisions of this Agreement will be sent to the addresses set out below, or to such other addresses as may be designated by one party to the other by notice pursuant hereto, by prepaid, certified air mail (which shall be deemed received by the other party on the seventh (7^{th}) business day following deposit in the mails) or nationally recognized overnight courier (which shall be deemed received upon verification of receipt), or by email (which shall be deemed received when transmitted, if during normal business hours, or on the recipient's next business day, if not sent during normal business hours):

if to CFF, at:

Cystic Fibrosis Foundation
6931 Arlington Rd., Suite 200
Bethesda, MD 20814
Attn: Michael Boyle, President and CEO
Phone: 240-200-3743
Email: mboyle@cff.org

with a copy (which shall not constitute notice) to:

Cystic Fibrosis Foundation
6931 Arlington Rd., Suite 200
Bethesda, MD 20814
Attn: Stephanie Singer, Senior Counsel
Phone: 240-200-3707
Email: ssinger@cff.org

if to the Awardee, at:

Matinas Biopharma NanoTechnologies, Inc
1545 Route 206 S
Suite 302
Bedminster, NJ 07921
Attn: Jerome Jabbour, CEO
Phone 908-505-0959
Email jjabbour@matinasbiopharma.com

(e) **Headings**. The paragraph headings are for convenience only and will not be deemed to affect in any way the language of the provisions to which they refer.

(f) **No Avoidance**. The Awardee will not, by amendment of its organizational or governing documents, or through reorganization, recapitalization, consolidation, merger, dissolution, sale, transfer or assignment of assets, issuance of securities, or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms, provisions, covenants or agreements of this Agreement.

(g) **Assignment**. This Agreement may not be assigned by any party without the consent of the other party which consent shall not be unreasonably withheld, delayed or conditioned; provided, however, that the Awardee may assign this Agreement, without the consent of CFF, to an Affiliate or to the acquiror of Awardee or its equity or assets pursuant to a Change of Control Transaction of Awardee or in the sale or license to a third party of the assets to which this Agreement relates. Awardee shall give prompt notice to CFF of any such assignment or transfer by operation of law.

(h) **No Relationship**. Nothing herein contained shall be deemed to create an agency, joint venture, amalgamation, partnership or similar relationship between CFF and the Awardee. Notwithstanding any of the provisions of this Agreement, neither party to this Agreement shall at any time enter into, incur, or hold itself out to third parties as having authority to enter into or incur, on behalf of the other party, any commitment, expense, or liability whatsoever, and all contracts, expenses and liabilities in connection with or relating to the obligations of each party under this Agreement shall be made, paid, and undertaken exclusively by such party on its own behalf and not as an agent or representative of the other.

(i) **Publicity**. The Awardee shall submit any proposed press release or other public announcement, other than an academic, scholarly, or scientific publication, concerning the terms of this Agreement or this Award prior to its public release, to the Public Affairs Department of CFF for approval prior to its public release, with sufficient time prior to its public release to allow for review and comment, except to the extent any such release or announcement is required by law, rule, or regulation or the rules of any securities exchange. The parties agree that they intend to advance the body of general scientific knowledge of cystic fibrosis and its potential therapies and cures and the parties acknowledge that the Awardee intends to, and CFF desires that the Awardee does, as commercially and scientifically reasonable based on the results of the Development Program, publish the results of the Development Program in a scientific peer-reviewed publication as soon as reasonably practicable. In furtherance of the foregoing, but subject to the Awardee's right to preserve and protect its confidential information and any information that if published would have an adverse effect on any patent application which the Awardee (or any Affiliate thereof, licensee or sublicensee of the Awardee or any Affiliate thereof, or contractor or collaborator of any of the foregoing) intends to file, the Awardee shall use commercially reasonable efforts to make available to academic third parties for non-commercial research purposes such tangible research materials or resources developed during the Development Program as the Awardee considers appropriate under the circumstances and under reasonable terms and conditions. CFF's support for the Development Program shall be acknowledged in any press releases and publications relating to the Development Program.

(j) **Anti-Terrorism**. In accordance with the U.S. Department of the Treasury Anti-Terrorist Financing Guidelines, the Awardee shall take reasonable steps to ensure that the payments received from CFF are not distributed to terrorists or their support networks or used for activities that support terrorism or terrorist organizations. The Awardee certifies that it is in compliance with all laws, statutes and regulations restricting U.S. persons from dealing with any individuals, entities, or groups subject to Office of Foreign Assets Control sanctions.

(k) **Amendments and Waiver**. Any amendment or waiver of any provision of this Agreement shall be in writing and signed by a duly authorized representative of each party. The delay or failure of a party at any time to require performance of any provision of this Agreement shall in no way affect such party's rights at a later time to enforce the same.

(l) **Entire Agreement**. This Agreement (including the Exhibits attached here) constitutes the entire agreement between the parties relating to the subject matter hereof and supersedes all prior or contemporaneous agreements, understandings or representations, either oral or written, between the parties with respect to such subject matter.

(m) **Force Majeure**. If the performance of any part of this Agreement by either party is prevented, restricted, interfered with or delayed by any reason of *force majeure* (including fire, flood, embargo, power shortage, pandemic or failure, acts of war, insurrection, riot, terrorism, strike, lockout or other labor disturbance or acts of God) (a "Force Majeure Event"), the party so affected shall, upon giving written notice to the other party, be excused from such performance to the extent of such prevention, restriction, interference or delay; provided, that the affected party shall use reasonable efforts to avoid or remove such causes of non-performance.

15. Definitions; Valuation Determination. Unless otherwise defined in this letter, the following shall apply:

(a) "**Actual Award**" means the total amount of the Award Amount actually paid to the Awardee, to the extent not returned by the Awardee to CFF pursuant to Section 2. For clarity, this includes the funds previously advanced to the Awardee pursuant to the prior Letter Agreements as well as the New Award Amount.

(b) "**Affiliate**" means, with respect to a party, any entity which directly or indirectly controls, is controlled by, or is under common control with, such party. For these purposes, "control" shall refer to (i) the ownership, directly or indirectly, of at least fifty percent (50%) of the voting securities or other ownership interest of an entity; or (ii) the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise.

(c) "**Award**" shall have the meaning set forth in Section 1 of the Agreement.

(d) "**Awardee Background IP**" shall mean any intellectual property rights that are (a) owned or controlled by Awardee prior to the Effective Date, (b) created, conceived or reduced to practice by Awardee independently from this Agreement or (c) acquired by Awardee from a third party after the Effective Date.

(e) "**CFF Know-How**" shall have the meaning set forth in Section 10(b).

(f) "**Change of Control Transaction**" means the consummation of a transaction, or a series of related transactions, constituting (i) a merger, share exchange or other reorganization of Awardee, following which the stockholders of the Awardee immediately prior to such transaction do not own a majority of the voting power of the acquiring, surviving or successor entity, (ii) the sale by one or more stockholders of a majority of the voting power of the Awardee, or (iii) a sale of all or substantially all of the assets of the Awardee (or that portion of its assets related to the subject matter of this Agreement). For purposes of clarity, and notwithstanding anything to the contrary, a Change of Control Transaction shall not include any bona fide financing transaction whose primary purpose is for the benefit of the Awardee (i.e. in which the Awardee raises capital for general working capital or other business purposes) in which one or more persons or entities acquire shares of the Awardee capital stock from the Awardee.

(g) "**COC Consideration**" means the consideration received by the Awardee and/or its equityholders in connection with the Change of Control, including up-front consideration and any payments due for any deferred or contingent consideration (including, without limitation, any post-closing milestone payment, escrow or holdback of consideration). The valuation of any securities or other property shall be determined by reference to the operative transaction agreement for the Merger, Stock Sale or Asset Sale, provided that if no such valuation is readily determinable from such operative transaction agreement, (i) the valuation of marketable securities shall be deemed to be the average of the closing prices of the securities on such exchange or market over the thirty (30) day period ending three days prior to the closing of such transaction, and (ii) the valuation of non-marketable securities shall be determined in good faith by the Board of Directors of the Awardee or, if such determination is objected to by CFF in writing within twenty (20) business days after CFF receives written notice thereof from the Awardee, by an independent, neutral third party appraiser agreed upon by the Awardee and CFF. The cost of such appraiser shall be borne by CFF or, if such appraiser's determination of such valuation is equal to or greater than one hundred ten percent (110%) of the valuation determined by the Awardee's Board of Directors, by the Awardee.

(h) "**Commercially Reasonable Efforts**" shall mean the level of effort, expertise and resources that is substantially and materially consistent with industry standards for companies of similar size and financial resources to research, develop and commercialize a Product where such research, development and commercialization is technically feasible, devoting the same degree of attention and diligence to such efforts that is substantially and materially consistent with industry standards for products at a comparable

stage in development (with similar market potential, and taking into account, without limitation, issues of safety and efficacy, proprietary position, the competitive environment, the regulatory environment, and other relevant scientific, technical and commercial factors) for companies of similar size and financial resources.

(i) "**Development Program Technology**" means all technology first created or conceived in whole, or developed directly or indirectly, as a result of the Development Program and owned or controlled by Awardee, excluding without limitation any Awardee Background IP.

(j) "**Field**" shall mean the treatment of pulmonary non-tubercular mycobacteria (NTM) infections and other pulmonary disease.

(k) "**Interruption**" means the cessation for more than one hundred eighty (180) consecutive days of Commercially Reasonable Efforts to develop a Product at any time before the first commercial sale of a Product, or to commercialize a Product following regulatory approval of a Product for sale for human therapeutic use. Notwithstanding the foregoing, delays resulting from events outside of the Awardee's reasonable control (e.g., technical difficulties, shortages of supplies or materials, delays in preclinical or clinical studies or regulatory processes, etc.) or Force Majeure will not be deemed cessation of the use of Commercially Reasonable Efforts.

(l) "**License**" means (a) the grant of rights to a third party that includes a license to the Development Program Technology in the Field, or (b) the grant of distribution or marketing rights to a third party with respect to a Product.

(m) "**License Revenue**" means all revenues and other consideration paid to the Awardee or to an Affiliate in consideration of a License. Without limiting the generality of the foregoing, License Revenue shall include, without limitation all upfront fees, license fees, milestone payments, technology access fees, premiums above the fair market value on sales of debt or equity securities of the Awardee or of an Affiliate, annual maintenance fees, and any other payments to the extent, in each case, received as consideration for the Awardee's or its Affiliate's grant of such license, distribution or marketing rights. Notwithstanding the foregoing, License Revenue shall exclude: (i) payments for debt or equity securities of the Awardee or an Affiliate thereof to the extent equal to or less than the fair market value of such securities as of the date of receipt of such payments as determined in good faith by the Awardee's Board of Directors; (ii) reimbursements or advances for any actual costs of patent preparation, filing, prosecution, maintenance, or defense incurred by the Awardee or its Affiliates with respect to the Development Program Technology or any other patent rights to which rights are granted to the applicable licensee; and (iii) payments made by a licensee as consideration for the Awardee's or an Affiliate's performance of services. The valuation of any securities or other property shall be determined by reference to the operative transaction agreement, provided that if no such valuation is readily determinable from such operative transaction agreement, (i) the valuation of marketable securities shall be deemed to be the average of the closing prices of the securities on such exchange or market over the thirty (30) day period ending three days prior to the closing of such transaction, and (ii) the valuation of non-marketable securities shall be determined in good faith by the Board of Directors of the Awardee or, if such determination is objected to by CFF in writing within twenty (20) business days after CFF receives written notice thereof from the Awardee, by an independent, neutral third party appraiser agreed upon by the Awardee and CFF. The cost of such appraiser shall be borne by CFF or, if such appraiser's determination of such valuation is equal to or greater than one hundred ten percent (110%) of the valuation determined by the Awardee's Board of Directors, by the Awardee.

(n) "**Net Sales**" means, for any period, the gross amount invoiced for sales of the Product by the Awardee or any Affiliate, licensee, sublicensee or transferee, as applicable (a "**Selling Person**"), to a non-Affiliate of such Selling Person, less the following deductions, in each case to the extent specifically related to the Product and taken by the Selling Person or otherwise paid for or accrued by the Selling Person ("**Permitted Deductions**"): (a) normal and customary trade, quantity, cash and/or other discounts, rebates, and sales returns and allowances, including (i) those granted on account of price adjustments (including retroactive price adjustments), billing errors, rejected goods, damaged goods, returns and rebates, (ii) administrative and other fees including inventory management fees and reimbursements and similar payments to wholesalers and other distributors, buying groups, pharmacy benefit management organizations, health care insurance carriers and other institutions, (iii) allowances, rebates and fees paid to distributors and (iv) chargebacks; (b) customs, excise, import, or export duties, tariffs, or similar payments; (c) rebates, chargebacks, and similar payments made with respect to sales paid for by any governmental or regulatory authority; (d) sales, value added, consumption, use, or similar taxes directly related to the sale, transfer, purchase, or delivery of the Product (but not including taxes assessed against the income derived from such sale, transfer, purchase, or delivery or similar taxes); (e) the cost of freight, postage, shipping, insurance, and special packaging; and (f) bad debt or uncollectible amounts . Notwithstanding anything to the contrary, Net Sales shall not include, and shall be deemed zero with respect to, (i) Products sold, supplied, or distributed for promotional use and (ii) Products sold, supplied, or distributed for research, development, clinical trials, compassionate use, or charitable purposes.

In the case of any sale or other disposal of a Product between or among the Selling Persons for resale, Net Sales shall be calculated as above only on the value charged or invoiced on the first arm's-length sale thereafter to a third party; provided that any subsequent sale of the Product (or any product produced or manufactured using the Product) by a Selling Person to a non-Affiliate of such Selling Person shall be included in Net Sales. In the case of any sale which is not invoiced or is delivered before invoice, Net Sales shall be calculated at the time the Product is paid for. In the case of any sale or other disposal for value, such as barter or counter-trade, of any Product, or part thereof, other than in an arm's length transaction exclusively for money, Net Sales shall be calculated as above on the fair market value of the consideration received.

(o) "**Product**" means MAT2501 and its formulations and derivatives, and any other oral amikacin developed in whole or in part as a result of the Development Program.

(p) "**Royalty Cap**" means an amount equal to five (5) times the amount of the Actual Award.

[*Remainder of this page intentionally left blank.*]

In witness whereof, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the dates set forth below.

Cystic Fibrosis Foundation

By: _____
Name: _____
Title: _____
Date: _____

Awardee
Matinas BioPharma Nanotechnologies, Inc.

By: _____
Name: _____
Title: _____
Date: _____

Exhibit A

Development Program Plan

[***]

Exhibit B

Payment Schedule

Award payments will be made based on the following schedule:

Milestone Payment Number	Development Program Milestone	Milestone Payment	Estimated Milestone Completion Date
1.	Agreement execution	$ 650,000	The date hereof
2.	[***]	$ [***]	[***]
3.	[***]	$ [***]	[***]
4.	[***]	$ [***]	[***]
5.	[***]	$ [***]	[***]

Upon the achievement of each Development Program Milestone, the Awardee shall prepare a report (each, a "**Milestone Report**") that includes: description of the work, summary data generated, interpretation of the data, and progress toward achieving the goals of the Development Program.

The Awardee shall submit an invoice and a corresponding Milestone Report within one month after achievement of each Development Program Milestone. Milestone Reports will be reviewed by the CFF Program Officer responsible for this Agreement.

Milestone payments will be made by CFF within forty-five (45) days of:

1. Receipt from the Awardee of a dated invoice, identifying Milestone Payment Number and corresponding Development Program Milestone;
2. Receipt from the Awardee of a written Milestone Report for the applicable Milestone Payment; and
3. Approval, by the responsible CFF Program Officer, of the Milestone Report.

All reports and documents must be submitted electronically to: grants@CFF.org

Exhibit 21.1

Subsidiaries of Matinas BioPharma Holdings, Inc.

Name	State of Incorporation
Matinas BioPharma, Inc.	Delaware
Matinas BioPharma Nanotechnologies, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements of Matinas BioPharma Holdings, Inc. and Subsidiaries on Form S-3 (No. 333-239675) and Form S-8 (Nos. 333-198488, 333-203141, 333-210495, 333-215456, 333-222912, 333-237315 and 333-253659) of our report dated March 29, 2021, on our audit of the consolidated financial statements as of December 31, 2020 and 2019 and for each of the years then ended, which report is included in this Annual Report on Form 10-K to be filed on or about March 29, 2021.

/s/ EISNERAMPER LLP

EISNERAMPER LLP
Iselin, New Jersey
March 29, 2021

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Jerome D. Jabbour, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2020 of Matinas BioPharma Holdings, Inc.;

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(s) 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(s) 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.

Date: March 29, 2021

/s/ Jerome D. Jabbour

Jerome D. Jabbour
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Keith A. Kucinski, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2020 of Matinas BioPharma Holdings, Inc.;

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(s) 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(s) 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.

Date: March 29, 2021

/s/ Keith A. Kucinski
Keith A. Kucinski
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF
THE PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(b)
OF THE SECURITIES EXCHANGE ACT OF 1934 AND 18 U.S.C. SECTION 1350

In connection with the Annual Report on Form 10-K of Matinas BioPharma Holdings, Inc. (the "Company") for the fiscal year ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Jerome D. Jabbour, Chief Executive Officer of the Company, and Keith A. Kucinski, Chief Financial Officer of the Company, hereby certify, to the knowledge of the undersigned, pursuant to 18 U.S.C. Section 1350, that:

(1) 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.

Date: March 29, 2021

/s/ Jerome D. Jabbour
Jerome D. Jabbour
Chief Executive Officer
(Principal Executive Officer)

Date: March 29, 2021

/s/ Keith A. Kucinski
Keith A. Kucinski
Chief Financial Officer
(Principal Financial and Accounting 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.