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

FORM 10-K

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

For the fiscal year ended December 31, 2018

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: None

Title of Class:	**Name of Each Exchange on Which Registered:**
Common Stock, par value $0.0001	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 [X]

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 [X]

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 [X] 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 [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

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	[X]	Smaller reporting company	[X]

Emerging growth company [X]

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 [X]

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, 2018 was approximately $33.7 million.

As of March 29, 2019, there were 142,937,626 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, 2018

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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 MAT9001, which are still in an early development stage;
- our reliance on proprietary lipid nano-crystal (LNC) drug delivery technology platform, which is licensed to us by Rutgers University;
- our ability to manufacture GMP batches of our product candidates, including MAT9001 and MAT2203, 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 expectations of the attributes of our product and development candidates, including pharmaceutical properties, efficacy, safety and dosing regimens including our anticipated market advantages and product differentiation of MAT9001, and its potential to become a best-in-class omega-3 therapeutic for the treatment of severe hypertriglyceridemia and potential to expand MAT9001's indication to the treatment of high TGs (200-499 mg/dL);
- our dependence on third-parties, including third-parties to manufacture products and third-party contract research organizations (including, without limitation, the National Institutes of Health (NIH)) 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;
- developments and projections relating to our competitors or our industry; and
- our ability to adequately support growth.

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 clinical-stage biopharmaceutical company focused on creating value through (i) the streamlined development under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA of our lead product candidate, MAT9001, a highly purified, prescription-only omega-3 free fatty acid formulation specifically designed for the treatment of cardiovascular and metabolic conditions and (ii) the application of our lipid nano-crystal (LNC) platform delivery technology to solve complex challenges relating to the delivery of small molecules, gene therapies, vaccines, proteins and peptides. In general, the development timeline for a 505(b)(2) New Drug Application, or NDA, is shorter and less expensive than an NDA developed under Section 505(b)(1) for new chemical entities that have never been approved in the United States. Based upon MAT9001's unique mixture of highly purified omega-3 free fatty acids and our observations of MAT9001's enhanced bioavailability and potency as compared to Amarin Corporation's Vascepa® (icosapent ethyl) in our initial head-to-head pharmacokinetic (PK) and pharmacodynamic (PD), or PK/PD, clinical study, we believe that the results of our forthcoming targeted clinical development activities and related clinical investigations may yield an improved therapeutic profile compared to currently-existing therapies.

MAT9001 is a soft gelatin capsule containing a complex mixture of polyunsaturated free fatty acids, including multiple long-chain omega-3 fatty acids, including primarily eicosapentanoic acid (EPA) and docosapentanoic acid (DPA). Amongst other properties, omega-3 fatty acids, which are also found in FDA-approved drugs in varying amounts, such as Vascepa®, have extensive clinical evidence of safety and efficacy in lowering triglycerides (TG) in patients with hypertriglyceridemia (HTG). We believe that based upon MAT9001's unique composition, which includes more DPA than other known omega-3 fatty acids, it will prove to be differentiated from other existing therapies for the treatment of very high triglycerides, or severe hypertriglyceridemia (SHTG), and dyslipidemia.

Triglycerides are fats that are carried in the blood, together with cholesterol, within lipoproteins. High levels of triglyceride-rich lipoproteins are associated with an increased risk of atherosclerotic cardiovascular disease and in the case of severe hypertriglyceridemia, acute pancreatitis. High levels of triglycerides are due to both genetic and environmental factors and are associated with comorbid conditions such as diabetes, chronic renal failure, and nephrotic syndrome. Unlike the currently approved products in this category, many of which have been repurposed following clinical failures in their originally intended indications, we have specifically designed and developed MAT9001 to treat SHTG, dyslipidemia and other cardiovascular and metabolic conditions.

In 2015, we announced results from our head-to-head PK/PD clinical study against Vascepa, a prescription-only ethyl ester formulation of EPA. This was an open-label, cross-over design study conducted in 42 patients with elevated triglyceride levels. Patients were treated for 14 days with MAT9001 or Vascepa, (4 grams/day for both treatment arms), followed by a five-week wash-out period, then crossed over to the other treatment. The main objectives of the study were to measure the relative bioavailability of MAT9001 versus Vascepa as well as effects on triglyceride levels. In this study, we observed statistical superiority of MAT90001 in reducing serum triglycerides, total- and non-HDL-cholesterol, apolipoprotein CIII and PCSK9 levels. MAT9001 was observed to significantly reduce PCSK9 in patients. In this trial, MAT9001 achieved greater median percentage reduction in four of six lipid measures, including total cholesterol, when compared to Vascepa.

We are focusing our initial efforts on developing MAT9001 with an initial indication for the treatment of severe hypertriglyceridemia. If we receive U.S. Food and Drug Administration (FDA) approval for severe hypertriglyceridemia, we may seek approval for use of MAT9001 in additional indications, including the treatment of patients with mixed dyslipidemia who are already undergoing treatment with a statin, a commonly used class of cholesterol-lowering medications.

Consistent with our strategy first put in place when we filed the investigational new drug (IND) application for MAT9001 in 2014, we intend to pursue a 505(b)(2) regulatory pathway towards NDA approval in the United States. Pursuant to this streamlined development approach, we are permitted to rely, at least in part, on FDA findings of safety and/or effectiveness for a previously approved drug. Based upon written feedback received from the FDA in 2014, 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 MAT9001 for the treatment of severe hypertriglyceridemia (≥500 mg/dL). Simultaneously with those preclinical and clinical studies necessary for approval of this initial indication, we intend to conduct two additional studies designed to highlight the differentiated profile of MAT9001 vs. market leading omega-3 fatty acids and potentially yielding superior data in similar patient populations to those data generated by already-approved omega-3 fatty acids. We believe this dual development strategy will best position MAT9001 to secure an approval to treat severe hypertriglyceridemia as quickly as possible while also positioning MAT9001 as the best-in-class prescription omega-3 therapy as this market and regulatory requirements evolve.

While we advance MAT9001 toward pivotal trials in the cardiovascular space, we are also determined to maximize the value associated with our unique and potentially disruptive lipid nano-crystal (LNC) platform delivery technology. Our proprietary LNC platform delivery technology, licensed from Rutgers University on an exclusive worldwide basis, nano-encapsulates molecules and is designed to render these molecules orally bioavailable, well-tolerated and safe via fusogenic intracellular delivery. We believe the ability of our drug delivery technology to efficiently deliver drugs intracellularly may result in the targeted and safe delivery of pharmaceuticals directly to the site of infection or inflammation as well as the potential to treat a variety of cell-based pathogens, diseases and conditions. We believe our cochleate technology provides us with a highly stable, efficient and broadly applicable drug delivery platform, that has the potential to deliver a broad range of therapies, including small molecules, vaccines, peptides and proteins, as well as nucleic acid polymers in the gene therapy space (e.g., siRNA, mRNA, and CRISPR/Cas-9) in diseases and conditions exhibited by inflammation (e.g., CNS and infectious diseases) as well as intracellular diseases (e.g., intracellular pathogen-related, genetic disorders, and cancer).

Our lead drug candidate based on the LNC platform is MAT2203, an oral formulation of amphotericin B, a well-known and highly-effective, antifungal drug (though traditionally highly-toxic 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 and the prevention of invasive fungal infections in patients who are on immunosuppressive therapy. We have completed two Phase 2 studies of MAT2203 since 2015 and, leading up to and following a meeting with the Office of Antimicrobial Products (OAP) in January 2018, we had been positioning MAT2203 for an initial indication for the prophylaxis, or prevention, of invasive infections in patients who are suffering from acute lymphoblastic leukemia (ALL) who are rendered immunosuppressed due to the therapies being utilized to treat these patients' leukemia.

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 believe there are opportunities for a potentially more rapid approval of MAT2203 for the treatment of certain invasive fungal infections in areas of high unmet medical need which can be substantially supported by non-dilutive government funds. In partnership with the NIH, we have conducted numerous preclinical studies of MAT2203 for the treatment of cryptococcal meningitis. 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 liposomal delivery of amphotericin B intravenously.

This data attracted the attention of several organizations, including the NIH, interested in finding a better treatment option for cryptococcal meningitis. The NIH recently approved and fully funded a grant submission from the University of Minnesota to conduct a clinical study of MAT2203 on patients with cryptococcal meningitis located in Uganda, Africa where this disease is very prevalent among the HIV-positive community. In consultation with the NIH and the University of Minnesota we are finalizing a protocol to commence this study during 2019. We believe that this clinical trial could become a registration-quality trial for an indication for MAT2203 to treat cryptococcal meningitis. We intend to finalize this protocol in the near term and then engage with the FDA to outline a potential pathway for approval of MAT2203 based upon this trial. Given the significant challenge associated with treating cryptococcal meningitis. Combined with the oral and targeted delivery and safety profile we believe the LNC platform delivery affords, we believe MAT2203 is well positioned to become a best-in-class antifungal drug. In addition, we believe that a demonstration that MAT2203 can effectively cross the blood-brain barrier in humans in this study could potentially position our LNC platform delivery technology to be utilized with molecules designed to treat diseases of the central nervous system exhibited by inflammation. Developing MAT2203 utilizing non-dilutive, government-sponsored, financing allows us to focus our internal cash resources on MAT9001 while advancing MAT2203 and our LNC platform technology into areas of significant unmet medical need and innovative medicine.

We have been engaged in discussions with various large, well-established and well-financed biotech and global pharmaceutical companies on potential applications of our LNC platform technology in the gene therapy space. Though early stage, these discussions have been based on existing data utilizing our LNC platform technology with complex nucleic acid polymers such as antisense oligonucleotides, mRNA, siRNA, and DNA plasmids. Our success in nano-encapsulating larger nucleic acids such as DNA plasmids, which can be as large as 11 kilobases in length, has also pushed us toward discussions with the NIH and others about utilizing our LNC platform delivery technology in the CRISPR-Cas9 space.

In July 2018, we announced a research collaboration with the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health (NIH), focused on the development of a novel therapy for the treatment of human immunodeficiency virus (HIV) combining targeted antisense oligonucleotides (ASO) and Matinas' LNC delivery technology. In January 2019 we announced a research evaluation with a top global pharmaceutical company in which our LNC platform technology would be explored in delivering certain nucleic acid polymers, and we continue to pursue additional strategic collaborations with other interested biotech and pharmaceutical partners.

We believe these early stage, proof-of-concept evaluations could provide a more efficient, less expensive pathway to create numerous strategic verticals in areas of innovative medicine relying upon the development expertise and financial resources of well-established pharmaceutical and biotech companies. Our belief is that data from these evaluations could position us to become 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 in order to utilize our LNC delivery platform technology.

Strategy

We are focused on creating value through the streamlined and strategic development of MAT9001 for the treatment of cardiovascular and metabolic conditions and the application of our LNC platform delivery technology to solve complex challenges relating to the delivery of small molecules, gene therapies, proteins/peptides, and vaccines. Key elements of our strategy include:

- Strategically advancing MAT9001 into clinical development toward an initial indication for the treatment of severe hypertriglyceridemia (≥500 mg/dL) (SHTG) with the goal of creating additional data further demonstrating the differentiation of MAT9001 from other prescription omega-3 drugs being used to treat a mixed dyslipidemic patient population in a rapidly emerging and expanding omega-3 market.

- Expanding application of our lipid nano-crystal (LNC) delivery platform into the gene therapy space through collaborations with sophisticated and well-resourced biotech and pharmaceutical companies in innovative areas of medicine.

- Driving MAT2203 to efficacy data in the treatment of cryptococcal meningitis, an area of significant unmet medical need, with the non-dilutive financial support of the NIH.

MAT9001

Our lead cardiovascular product candidate, MAT9001, is a proprietary prescription-only omega-3 fatty acid composition, comprised of a complex mixture of omega-3 fatty acids, including eicosapentaenoic acid, or EPA, docosapentaenoic acid, or DPA, several other omega-3 fatty acids, and relatively nominal amounts of docosahexaenoic acid, or DHA, and non-omega-3 fatty acids. We believe that based upon MAT9001's unique composition, which includes more DPA than other known omega-3 fatty acids, it will prove to be differentiated from other existing therapies for the treatment of very high triglycerides, or severe hypertriglyceridemia, and dyslipidemia. Triglycerides are fats that are carried in the blood, together with cholesterol, within lipoproteins. High levels of triglyceride rich lipoproteins are associated with an increased risk of atherosclerotic cardiovascular disease and in the case of severe hypertriglyceridemia, acute pancreatitis. High levels of triglycerides are due to both genetic and environmental factors and are associated with comorbid conditions such as diabetes, chronic renal failure and nephrotic syndrome. Unlike the current approved therapies in this product category, many of which have been repurposed following clinical failures in their originally intended indications, we have specifically designed and developed MAT9001 to treat severe hypertriglyceridemia and dyslipidemia. We believe that the results of these targeted development activities and related clinical investigations may yield an improved therapeutic profile compared to the currently-existing therapies, characterized most importantly by MAT9001's differentiating mechanistic features associated with its unique high DPA composition and enhanced potency as observed in our head to head clinical trial versus Vascepa.

We are primarily focused on developing MAT9001 through approval by the FDA, with an initial indication for the treatment of severe hypertriglyceridemia. Severe hypertriglyceridemia refers to a condition in which patients have high blood levels of triglycerides (TG ≥ 500 mg/dl) and is recognized as an independent risk factor for pancreatitis and cardiovascular disease. If we receive FDA approval for severe hypertriglyceridemia, we may seek approval for use of MAT9001 in additional indications, including the treatment of patients with mixed dyslipidemia who are already undergoing treatment with a statin, a commonly used class of cholesterol lowering medications. 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 NCEP Guidelines, we estimate that approximately 30 to 35 million Americans have mixed dyslipidemia.

Hypertriglyceridemia and Cardiovascular Disease Market Overview

Hypertriglyceridemia refers to a condition in which patients have levels of triglycerides in their blood above 200 mg/dL. Severe hypertriglyceridemia refers to a condition involving levels of triglycerides equal or above 500 mg/dL. Triglycerides (TG) are fats that are carried in the blood, together with cholesterol and lipoproteins. High levels of triglyceride-rich lipoproteins are associated with an increased risk of atherosclerotic cardiovascular disease. Hypertriglyceridemia is due to both genetic and environmental factors. Environmental factors include obesity, sedentary lifestyle, and high caloric diets. Hypertriglyceridemia is also associated with comorbid conditions such as diabetes, chronic renal failure, and nephrotic syndrome.

The prevalence of hypertriglyceridemia is rapidly increasing in the United States and throughout the world, correlating with the increasing incidence of obesity. Severe hypertriglyceridemia is also associated with markedly increased risk for cardiovascular disease and recent studies have demonstrated that elevated triglyceride levels can be regarded as an independent risk factor for cardiovascular disease-related events such as myocardial infarction, ischemic heart disease, and ischemic stroke.

Heart attacks, strokes and other cardiovascular events represent the leading cause of death and disability among men and women in western societies. More than 1 out of every 3 adults in the United States (approximately 92 million) currently lives 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; an estimated 29 million adults ≥20 years of age have high total serum cholesterol levels (≥240 mg/dL), and an estimated 71 million adults ≥20 years of age have borderline high or high low-density lipoprotein (“bad”) cholesterol, or LDL-C, levels (≥130 mg/dL).

In addition to cholesterol, lipoproteins such as LDL also carry fats in the form of triglycerides. Hypertriglyceridemia refers to a condition in which patients have high levels of triglycerides in the bloodstream and has been reported to be an independent risk factor for cardiovascular disease. Triglyceride levels provide important information as a marker associated with the risk for heart disease and stroke.

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. 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).

It is estimated that over 25 million adults in the United States have elevated triglyceride levels ≥200 mg/dL and that more than 50 million adults in the United States have elevated triglyceride levels ≥150 mg/dL. Additionally, approximately 4 million adults in the United States have very high triglyceride levels (≥500 mg/dL).

Mixed dyslipidemia refers to a condition in which patients have a combination of two or more lipid abnormalities including elevated triglycerides, low HDL-C, and/or elevated LDL-C. Both hypertriglyceridemia and mixed dyslipidemia are components of a range of lipid disorders collectively referred to as dyslipidemia. Dyslipidemia has been linked to atherosclerosis, commonly referred to as hardening of the arteries.

Limitations of Current Therapies

Hypertriglyceridemia (HTG) is a prevalent lipid disorder in approximately 25% of the U.S. adult population. Both epidemiological and genetic data have shown associations between HTG and coronary heart disease. Many of those patients are taking statin therapy directed at lowering the risk of cardiovascular disease (CVD) by lowering their LDL-C levels, primarily. Recently, real world administrative database analyses have reported an increased CVD risk as well as direct healthcare costs associated with HTG despite statin therapy and controlled LDL-C compared to those with TG<150 mg/dL.

There is currently no approved prescription omega-3 to lower TG levels in statin-treated patients with mixed dyslipidemia and persistent high (≥200 mg/dL and <500 mg/dL) TG levels due to uncertainty raised by FDA in 2013 regarding the benefit, if any, of drug-induced changes in lipid/lipoprotein parameters beyond statin-lowered LDL-C on cardiovascular risk among statin-treated patients with residually high TG.

Additionally, recent cardiovascular (CV) outcomes trials and meta-analyses with low dose omega-3 fatty acid mixtures containing DHA have not shown substantial benefit in patients receiving contemporary medical therapy, including statins. Due to these failed low dose omega-3 CV outcomes trials, the European regulatory authorities have concluded that omega-3 fatty acid medicines at a dose of 1-gram per day are not effective in preventing further events for patients who have had a heart attack.

TG levels provide important information as a marker associate with the risk for heart disease and stroke, especially when an individual also has low levels of high-density lipoprotein cholesterol (HDL-C) and elevated levels of low-density lipoprotein cholesterol (LDL-C). Multiple epidemiological, clinical, and genetic studies suggest that patients with elevated TG levels (>=200 mg/dL) are at a greater risk of coronary artery disease (CAD) and pancreatitis, a life-threatening condition, as compared to those with normal TG levels. The genes regulating TGs and LDL-C are equally strong predictors of CAD, unlike HDL-C which is not. Other studies suggest that managing and lowering TG levels may reduce these risks.

Currently Available Treatment Options and Market Opportunity

The dramatic rise in obesity over the last few decades has led to a concomitant increase in cholesterol and triglyceride levels among the population. The collective term for high blood lipid levels such as high cholesterol and high triglyceride levels often used is “dyslipidemia.” Observational studies have resulted in an increased awareness of the critical role that high cholesterol and high triglyceride levels 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 that is not effective, dyslipidemia is then often treated with statins, which account for approximately 80% of all dyslipidemia prescriptions. Statins became a highly successful class of medications for the treatment of dyslipidemia due to their ability to reduce cardiovascular risk in patients at high risk for heart attacks, strokes, and other adverse cardiovascular events. Because of these outcome benefits, the statin utilization rate as compared to the incidence and prevalence of dyslipidemia in the general population, which we refer to as the epidemiology, has risen to almost 40% in the United States. However, the primary activity of statins is in the reduction of LDL-cholesterol levels and they have only modest effects on triglyceride levels. Recognizing that statins alone are not very effective triglyceride lowering drugs, the National Cholesterol Education Program panel recommends the use of more focused therapies to lower triglyceride levels in patients with severe hypertriglyceridemia. Fibrates (a class of amphipathic carboxylic acids), omega-3 fatty acid-based medications and niacin have all been utilized to lower triglycerides levels. In patients with severe hypertriglyceridemia, first-line drug therapy is often a prescription omega-3 or fibrate. Prescription omega-3 based products have been shown to reduce triglyceride levels in the range of 20%-45%.

The treatment rate of hypertriglyceridemia has remained relatively low – below ten percent - compared to the adult population with hypertriglyceridemia. Historically, fibrates such as gemfibrozil (Lopid) and fenofibrate (Tricor or Trilipix) have led the class of treatments of hypertriglyceridemia. However, due to their inability to establish clinical outcome benefits and their limited compatibility with statin therapy, the fibrate utilization rate has remained relatively low and is currently declining. Other products used to treat severe hypertriglyceridemia incorporating niacin as the active pharmaceutical ingredient have not been able to establish additional outcome benefits as compared to statin treatment alone, and are also encountering declining utilization. Because of their lack of outcome benefits, fibrate and niacin use has been mostly concentrated in severe hypertriglyceridemia.

Many omega-3 fatty acid based products have anti-thrombotic and anti-inflammatory effects that suggest effectiveness in inhibiting atherosclerosis in animal models as well as reducing the rate of adverse cardiovascular events in humans at high risk for such events as demonstrated in the JELIS Trial and the GISSI Prevenzione trial in Italy. Furthermore, omega-3 fatty acid based products, either concentrates of both EPA and DHA or EPA alone, have been demonstrated in multiple clinical trials to lower serum concentrations in patients with hypertriglyceridemia. In a recent third-party study, increased levels of EPA and DHA in red blood cells directly correlated with significant reductions in cardiovascular health risks. However, omega-3 fatty acid based medications with significant levels of DHA have been shown to increase LDL-cholesterol levels, which is a negative side effect.

The global prescription omega-3 market has been growing steadily over the last two decades and 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 hypertriglyceridemia are Glaxo Smith Kline's Lovaza (omega-3-acid ethyl esters, an omega-3 mixture containing mostly EPA and DHA, branded as Omacor in the rest of the world), Omacor and Seacor, very similar to Lovaza and marketed in Europe; and Mochida Pharmaceutical Co., Ltd's ("Mochida") Epadel (98% ethyl eicosapentaenoate), the leading Japanese omega-3 product. Recently, a new omega-3 based medication, Amarin's Vascepa (97% ethyl eicosapentaenoate), was approved and launched in the United States. In addition, Astra Zeneca has an FDA-approved product, Epanova, which has not yet been launched.

MAT9001 Differentiation Strategy

In contrast to certain other omega-3 based prescription products, MAT9001 is not a product repurposed from a previous development program for another disease or condition, as it was specifically designed for the treatment of severe hypertriglyceridemia and mixed dyslipidemia. Specifically, we are pursuing two avenues of differentiation from existing products, including Vascepa and Lovaza:

1. MAT9001 has unique mechanistic features due to its proprietary composition of omega-3 fatty acids, including DPA, which we believe is a key differentiating omega-3 fatty acid component (*i.e.*, a component that is neither EPA nor DHA); and

2. MAT9001 is designed to have a highly concentrated potency versus other omega-3 products due to its free fatty acid formulation and potentially improved bioavailability relative to other omega-3 fatty acid pharmaceutical products, as demonstrated in our head to head study against Vascepa. Unlike ethyl-ester omega-3 fatty acid formulations, MAT9001 does not require enzymatic breakdown in the small intestine before it can be adequately absorbed. These enzymes are secreted in the intestine in response to dietary fats. Therefore, ethyl-ester omega-3 fatty acids are not optimally absorbed unless they are taken with a high-fat meal, which is contraindicated in patients with hypertriglyceridemia. Because MAT9001 is less reliant on meal-fat content for optimal absorption, it has significantly greater bioavailability than the ethyl-ester form under the recommended low-fat diet conditions.

We believe that based upon both publicly available preclinical and human data generated with MAT9001, as well as independent data associated with one of the key omega-3 components contained in MAT9001, our product has the potential to:

1. Better control cholesterol, and may decrease low-density lipoproteins, or LDL, cholesterol levels;

2. Demonstrate superior reduction across numerous lipid biomarkers, including triglycerides, VLDL, non-HDL and Apo-C3 levels; and

3. Produce certain gene regulatory effects, such as the down regulation of HMG-CoA reductase and PCSK9.

In addition, MAT9001 contains a much lower concentration of DHA than certain competitive omega-3 products, such as Lovaza or Epanova (products with mixtures of mostly EPA and DHA). As described above, these products reduce triglycerides as the main desired effect but also have the negative side effect of increasing LDL-cholesterol levels. This side effect is observed with the use of Lovaza and Epanova in patients with severe hypertriglyceredemia as well as in patients with mixed dyslipidemia. In contrast, products with very low concentrations of DHA, such as Vascepa, have not shown the increase in LDL-cholesterol levels relative to placebo in either the severe hypertriglyceridemia or mixed dyslipedemia patient populations. Omega-3 products containing low DHA levels have also demonstrated reductions in LDL-cholesterol and non-HDL-cholesterol levels. We believe MAT9001's unique composition will produce differentiating results in reducing both cholesterol and triglyceride levels. Further, based on our product design, we believe that MAT9001 is well-positioned to become a leading treatment for severe hypertriglyceridemia if approved by the FDA.

MAT9001's free fatty acid form of omega-3 differentiates it from competitors and we believe this distinction leads to numerous clinical advantages. In a head to head study vs. Vascepa, as detailed further below, improved absorption characteristics and bioavailability were observed for MAT9001 as compared to Vascepa. Our PK/PD head-to-head trial compared the bioavailability of MAT9001 and Vascepa and it was observed that MAT9001's free fatty acid form was less reliant on meal-fat content for optimal absorption than Vascepa's ethyl-ester omega-3 form, which requires a high-fat meal for optimal absorption. It was also observed that patients on a low-fat diet exhibited five times higher blood plasma levels of EPA relative to Vascepa. Additional benefits of MAT9001's improved bioavailability may include once-a-day dosing, reduced pill burden and accompanying heightened patient compliance. All adverse events (AEs) reported in this study (whether related or unrelated to study drugs) were mild or moderate in severity. The most commonly reported AEs judged as possibly related to the study drug were dry skin and rhinorrhea. No serious adverse events (SAEs) were reported during the conduct of this study. The study medications were well-tolerated by patients in this study as well.

We believe that MAT9001, with its unique ratios of omega-3 free fatty acids, increased plasma concentrations of EPA compared to Vascepa, potential once-a-day dosing convenience, and observed degree of bioavailability and potential to reduce triglyceride levels as observed in our studies to date, is well-positioned to address significant unmet medical need and become a standard of care in the treatment of hypertriglyceridemia. Furthermore, we believe that MAT9001, due to the gene regulatory effects of DPA, in combination with statins, if approved by FDA, could become a standard of care in patients with mixed dyslipidemia with a prescribing and commercial advantage favoring products with a once per day dosing convenience similar to statins.

Development History

We believe we have optimized the manufacturing process for the active pharmaceutical ingredient of MAT9001 and have completed various preclinical studies and one human clinical trial with the MAT9001 active ingredient. We completed the first preclinical studies of MAT9001 in 2013 with others completed during 2014. In 2015, we announced results from our Head-to-Head PK/PD Trial against Vascepa in which we observed statistical superiority in reducing serum triglycerides, total- and non-HDL-cholesterol, apolipoprotein CIII and PCSK9 levels. The study was a pharmacokinetic and pharmacodynamic, open-label crossover study designed to compare the bioavailability and effects of MAT9001 versus Vascepa on serum triglyceride levels. Forty-two patients were treated with 4 grams/day of MAT9001 or Vascepa for 14 days, followed by a wash-out period and crossed over to the other treatment arm. Study subjects had 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. MAT9001 was observed to significantly reduce PCSK9 in patients. In this trial, MAT9001 achieved greater median percentage reduction in four of six lipid measures, including total cholesterol, when compared to Vascepa:

- MAT9001 significantly reduced median TG levels by 33.2 percent compared to 10.5 percent for Vascepa (p-value <0.001);
- MAT9001 significantly reduced median very low-density lipoprotein cholesterol (VLDL-C) levels by 32.5 percent compared to 8.1 percent for Vascepa (p-value <0.001);
- MAT9001 significantly reduced median non-HDL-C levels by 8.8 percent compared to 4.6 percent for Vascepa (p-value=0.027);
- MAT9001reduced median HDL-C levels by 11.3 percent compared to 11.1 percent for Vascepa (p-value= 0.337);
- MAT9001 reduced median LDL-C levels by 2.4 percent compared to 4.3 percent for Vascepa (p-value=0.116); and
- MAT9001 significantly reduced median total cholesterol levels by 9 percent compared to 6.2 percent for Vascepa (p-value=0.013).

MAT9001 also outperformed Vascepa in reductions in apolipoproteins (apo) and PCSK9 as compared to baseline:

- MAT9001 reduced median apolipoprotein B levels by 3.8 percent compared to 0.7 percent for Vascepa (p-value=0.058);
- MAT9001 significantly reduced median apolipoprotein AI levels by 15.3 percent compared to 10.2 percent for Vascepa (p-value=0.003);
- MAT9001 significantly reduced median apolipoprotein CIII levels by 25.5 percent compared to 5 percent for Vascepa (p-value=0.006); and
- MAT9001 significantly reduced median PCSK9 levels by 12.3 percent compared to an 8.8 percent increase in PCSK9 levels for Vascepa (p-value <0.001).

Pre-treatment median values for lipids, triglycerides, apolipoproteins, and PCSK9 levels were measured. Patients were randomized and put on MAT9001 or Vascepa for 14 days. Following the initial treatment period, there was a 5-week washout period, following which patients were put on the other therapy for 14 days. Forty patients completed the trial. MAT9001 met its primary PK endpoint for bioavailability of omega-3 for MAT9001 relative to Vascepa in this study. Statistical analysis demonstrated superiority of MAT9001 over Vascepa for omega-3 bioavailability (baseline adjusted AUC and C_{max}, approximately 6-fold higher with MAT9001 on Day 14, with very high statistical significance).

MAT9001 Development Plan

Following announcement of our head to head study vs. Vascepa in 2015, due primarily to cardiovascular regulatory and commercial market conditions, as well as limited financial resources, we determined to slow down development of MAT9001 until such time as data became available from Amarin's cardiovascular outcomes trial, REDUCE-IT™.

Following the release of data from the Amarin REDUCE-IT trial, we have re-initiated our development efforts and activities for MAT9001. With the support of a world-class team of key opinion leaders, clinicians and regulatory experts we have designed a development program for MAT9001 designed to (a) potentially streamline our path to approval for MAT9001 in its initial indication to treat severe hypertriglyceridemia and, (b) create additional data both head to head vs. Vascepa and in a mixed dyslipidemic patient population in order to position MAT9001 to become the potential best-in-class omega-3 prescription product for the treatment and prevention of cardiovascular conditions. Our regulatory strategy with FDA will include leveraging a 505(b)(2) registration pathway, consistent with the feedback we received from FDA during 2014. We are in the process of reactivating our IND and expect to complete this activity in the second quarter of 2019.

Pursuant to our development strategy, we intend to advance MAT9001 into a series of clinical trials designed to (a) complete those studies required for approval of an initial indication to treat severe hypertriglyceridemia (≥500mg/dL) and, (b) complete additional trials to demonstrate the differentiation of MAT9001 vs. competitive approved omega-3 products and also create the potential for label enhancement in a mixed dyslipidemic patient population (patients with triglyceride levels 200-499 mg/dL).

During 2019 we intend to initiate and complete the following studies (a) a 28-day comparative bridging toxicology study, and (b)subject to any feedback from FDA, a comparative clinical bioavailability study (36 healthy volunteers) with key endpoints and assessments to 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 MAT9001 after a high fat meal and also fasting vs. fed.

Following completion of these studies, we intend to request an End-of-Phase 2 Meeting with FDA to review the data from the completed studies and to gain a Special Protocol Assessment (SPA) on our pivotal study protocol for the treatment of severe hypertriglyceridemia. During this meeting, we intend to present the design of a Phase 3 registration study in SHTG patients. We anticipate, subject to feedback from FDA, that the study will be a placebo-controlled study with two dose groups of MAT9001: 2 gram and 4 gram/day. We anticipate that approximately 270 patients will be randomized 1:1:1. It is planned that MAT9001 will be dosed either once or twice daily without regard to meals. The primary endpoint of the study is anticipated to be change in TG levels at Week 12.

In addition to the studies required for approval to treat SHTG, we intend to conduct additional trials, including a comparative PK/PD study vs. Vascepa and a second Phase 3 trial of MAT9001 as an add-on to statin therapy in patients with high triglycerides (200-499 mg/dL) at risk for cardiovascular disease. We anticipate that our second head to head study vs. Vascepa will generate topline data during the second half of 2020.

MAT2203 - Our Lead Product Using our LNC Delivery Platform Technology

We have leveraged our platform lipid nano-crystal (LNC) platform delivery technology to develop two clinical-stage products that we believe have the potential to become best-in-class drug. Our lead LNC platform product candidate, MAT2203, is an orally-administered LNC formulation of a broad spectrum anti-fungal drug called amphotericin B. We previously had been planning to conduct a Phase 2/3 adaptive-design study of MAT2203 in patients with Acute Lymphoblastic Leukemia (ALL) for the prevention of invasive fungal infections (IFI) due to immunosuppressive therapy. 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 believe there are opportunities for a potentially more rapid approval of MAT2203 for the treatment of certain invasive fungal infections in areas of high unmet medical need which can be substantially supported by non-dilutive government funds. In partnership with the NIH, we have conducted numerous preclinical studies of MAT2203 for the treatment of cryptococcal meningitis. 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 liposomal delivery of amphotericin B intravenously.

We now plan to initially develop MAT2203 for the treatment of cryptococcal meningitis, one of the most frequent and opportunistic infections in Human Immuno-Deficiency Virus (HIV) patients. Given the high morbidity associated with cryptococcal meningitis 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 the 505(b)(2) regulatory pathway for MAT2203, in part relying upon FDA's findings of the efficacy of amphotericin B, and anticipate meeting with the FDA in the first half of 2019 to discuss our development plans for MAT2203. We also plan to seek accelerated approval for this indication. We are in the final planning stages for a Phase 2 clinical trial, fully funded by the NIH and conducted by the University of Minnesota at their clinic in Uganda. We believe that this study may have the potential to become a pivotal study to support approval of MAT2203 for the treatment of cryptococcal meningitis, and we also plan to submit an application for Orphan Designation and QIDP Designation during the first half of 2019.

Our second clinical stage LNC-based product candidate is MAT2501, an orally administered, cochleate 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. We have decided to temporarily halt clinical development of MAT2501, in order to prioritize and accelerate the development of MAT9001 and MAT2203 and explore utilization of our LNC platform delivery technology in the gene therapy space.

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 in other antifungal therapies. Currently, IV-only administered amphotericin B is the only broad spectrum fungicidal; however, it has significant treatment-limiting side effects, most notably nephrotoxicity. 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. 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 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 National Institutes of Health, four out of four enrolled patients met their primary efficacy endpoint, three patients continue on treatment of which two have been successfully taking MAT2203 for more than two years as part of a long term safety extension, with no evidence of kidney or other toxicity frequently associated with the use of amphotericin B.

Antifungal Market Opportunity

The overall global antifungal market accounted for $10.7 billion in 2015 with estimated annual worldwide sales of prescription systemic antifungal drugs reaching approximately $4 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, 6,000 for invasive aspergillosis, and 3,000 for cryptococcal meningitis. 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.

Our Solution – MAT2203

Our lead anti-infective product candidate, MAT2203, is an application of our LNC platform delivery technology to a broad spectrum anti-fungal drug called amphotericin B. 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 circulating amphotericin B. By reducing the amount of circulating drug, our LNC may reduce overall toxicity. Importantly, drug concentrations will be high only in tissues due to the migratory nature of macrophages 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 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 cryptococcal meningitis mouse models that our LNC-delivered amphotericin B, following oral administration, has the ability to 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 cryptococcal meningitis 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 cochleate drug delivery platform to provide higher drug exposure early in the course of therapy.

- **Enabling an all-oral therapy.** Cryptococcal meningitis has become the most common cause of adult meningitis in many parts of Africa, where cryptococcosis now rivals tuberculosis in all-case 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 cryptococcal meningitis 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 and for the prevention of IFIs in patients on immunosuppressive therapy. We are in the process of applying for a fourth QIDP for the treatment of cryptococcal meningitis. We will also apply for Orphan Drug Designation for MAT2203 for the treatment of cryptococcal meningitis. 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 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. Orphan drug exclusivity means that the FDA may not approved 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. Our plan is to further secure QIDP/Fast Track/Orphan Designation for the initial development target indication of cryptococcal meningitis.

Development History of MAT2203 and Initial Target Indication

MAT2203 was studied in animal model studies of various fungal infections including invasive candidiasis, aspergillosis and cryptococcal meningitis.

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

- The lipid-crystal nano-particle 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 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.

NIH-Conducted Study

In early 2017, we reported interim data from the NIH-Conducted Phase 2a Clinical Study of Orally-Administered MAT2203 for the Treatment of Chronic Refractory Mucocutaneous Candidiasis. At that time, two out of the two patients with long-standing azole resistant mucocutaneous candidiasis met the primary endpoint of the Phase 2a study, achieving ≥ 50% clinical response with treatment of MAT2203. Patient #01 achieved a 57% reduction in clinical symptoms after 8 weeks on therapy while patient #02 achieved an 85% reduction in such clinical symptoms after 6 weeks of treatment. MAT2203 was well tolerated with majority of adverse events observed being mild in severity and mostly unrelated to study drug. Importantly, for both patients renal and liver function parameters remained well within normal ranges during the core study as well as during the first 6-month extension of this study. In July 2017, the NIH/NIAID institutional review board approved continuation of treatment of patients in the study-extension for an additional 6 months, for total extension of up to one year.

In January 2018, the National Institutes of Health ("NIH") reported positive data from a third patient enrolled in this study. This third patient, with long-standing azole resistant mucocutaneous candidiasis, met the primary endpoint of the Phase 2a study in achieving ≥ 50% clinical response with treatment of MAT2203. MAT2203 was well tolerated with any adverse events observed being mild in severity and unrelated to study drug. With this third positive response, the study has met its statistical hurdle for success. In June of 2018, the NIH reported that a fourth patient had enrolled in the study and had met the primary endpoint in achieving ≥ 50% clinical response with treatment of MAT2203. All four patients had been enrolled in a long-term study extension and the initial two patients have now shown no signs of kidney or liver toxicity over the approximately twenty-four months of being administered MAT2203. The third patient was required to drop out of the long-term safety portion of the study due to the development of an infection that does not respond to amphotericin B. The fourth patient continues in the long-term safety extension for the study. The clinical response to MAT2203 seen in all three patients continuing on drug has been maintained and/or improved during the extension period in addition to patients reporting meaningful quality-of-life improvements.

VVC Study

In late 2017, we announced the topline data from our Phase 2 study in Vulvovaginal Candidiasis (VVC) using MAT2203. In the context of our overall program for MAT2203 with the aim to develop our lead product initially for the prevention of invasive fungal infections in patients who are immunocompromised due to immunosuppressive therapy, our goal was, in addition to further establishing the safety and tolerability of MAT2203, to demonstrate efficacy of MAT2203 through a mechanism involving systemic absorption in a non-life threatening fungal infection. This study concept was consistent with early human efficacy studies in the development of other anti- fungal therapies. This Phase 2 study was not designed or powered to support an indication for the treatment of VVC and therefore supplant fluconazole as the standard of care. The key data generated from this study included additional safety and tolerability data.

In this VVC study, the primary endpoint of safety was met, and it was demonstrated that oral delivery of encochleated amphotericin B is safe and well tolerated without the renal and hepatic toxicities that can be seen with administration of intravenous amphotericin B. Drug-related treatment emergent adverse events in this study were mostly of mild and gastro-intestinal nature and were seen at a rate of 20%, 18% and 2% respectively for MAT2203 200mg, MAT2203 400mg, and fluconazole. Consistent with the safety observations in the NIH study, in this VVC study no drug-related effects on liver function were observed and kidney function parameters stayed within normal ranges during the entire study for all 91 patients treated with MAT2203 for 5 days.

Development Plan

In February 2019, the NIH approved the funding of a planned clinical trial related to a grant application submitted by The University of Minnesota to study MAT2203 for the treatment of cryptococcal meningitis. The clinical study will be conducted in Uganda and has already received the approval of all necessary regulatory authorities. The protocol is in the process of being finalized and the trial is anticipated to consist of two parts with the following design. The initial portion of the trial will be a Phase 1 Study conducted in HIV patients in Uganda without active neurological infection. Subjects in this initial phase of the study will involve a determination of the maximal tolerated dose to arrive at an optimal dose for the second part of the study. A Data Monitoring Committee (DMC) will review the data from the initial phase prior to commencing the efficacy portion of the trial. Upon review of the data, the DMC will make a recommendation to the Ethics Committee/IRB as to the dose to be used in the efficacy portion of the study in patients with active neurological infection. The efficacy portion of the study has been designed as an open-label trial to evaluate the safety, tolerability, and microbiologic efficacy of oral MAT2203 as part of induction and consolidation treatment of HIV-infected patients with cryptococcal meningitis compared with standard intravenously delivered amphotericin B. Participants in the study will be enrolled in sequential cohorts designed to mitigate the risk associated with these very sick patients. Induction treatment in each cohort will start with IV amphotericin and flucytosine treatment with oral MAT2203 administered as step-down treatment for the initial two cohorts (with earlier step-down to MAT2203 in each subsequent cohort.) The next two cohorts will test the induction of treatment with our MAT2203 product, with step-down treatment to IV amphotericin. The final cohort of patients will have a MAT2203 induction treatment (plus flucytosine) without IV administered amphotericin B. The primary endpoint for this trial will be the rate of cerebrospinal fluid (CSF) Cryptococcus clearance as measured by serial quantitative CSF fungal cultures. This study is planned to commence in the second half of 2019. The trial design is expected to be finalized during 2019 following a meeting with FDA.

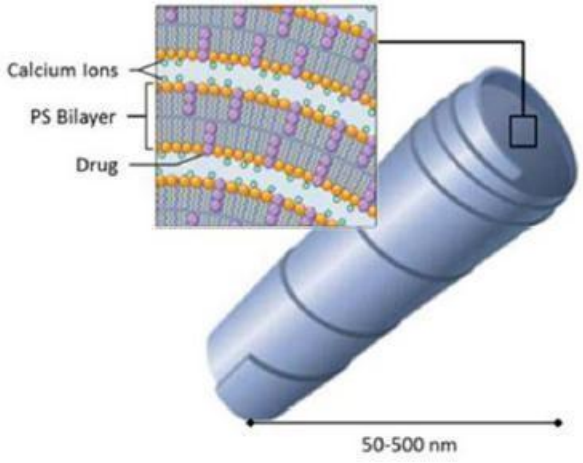
We are currently completing a 90-day rat toxicology study to support dosing with MAT2203 beyond the current 28-day tox coverage. The in-life portion of the study has been completed. There have been no signs of toxicity noted to date.

Our plan is to meet with FDA to review our development plan and study design as we intend to conduct this Phase 2 study in patients with cryptococcal meningitis under a US IND. We additionally will discuss with FDA our plans to leverage a 505(b)(2) Pathway, relying, in part, upon FDA's findings of safety and efficacy of I.V. amphotericin B.

Our Cochleate Platform Delivery Technology

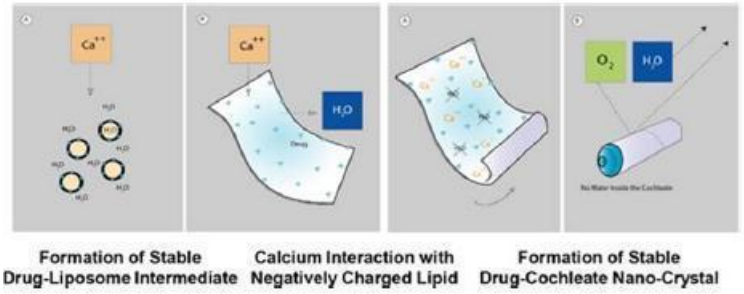
Cochleate lipid-crystal nano-particles are composed of simple, naturally occurring materials: phosphatidylserine (PS) and calcium. They are stable and have a unique multilayered structure consisting of a large, continuous, solid, lipid bilayer sheet rolled up in a spiral or as stacked sheets, with no internal aqueous space (Figure 1). This unique structure provides protection from degradation for "encochleated" molecules. Components within the interior of the cochleate remain intact, even though the outer layers of the cochleate may be exposed to harsh environmental conditions or enzymes.

Figure 1 Cochleate Formulation



The structure is formed when a series of solid lipid sheets engulf drug molecules, a process referred to as “encochleation.” Encochleation, developed by Matinas and Rutgers New Jersey Medical School, involves combining calcium and soy-derived PS, two naturally occurring materials classified as GRAS (generally recognized as safe), through a stirring process to envelop the active pharmacological ingredient. The result is a nano-size encochleated drug formulation (Figure 2).

Figure 2 Formation of Cochleate



Cochleates 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. Cochleates work by encapsulating molecules of drugs in a solid, anhydrous, crystalline structure, protecting them as they pass through the gastrointestinal (GI) tract where they cross the mucous membrane. Once the cochleates have crossed the mucosal barrier of the GI tract into the lymphatic system, they are picked up by particle scavenging cells of the mononuclear phagocytic system, such as macrophages and dendritic cells. (Figure 3). Activated macrophages, with drug-cochleate inside, migrate to the site of infection or to the target organ and deliver amphotericin B.

Cells in the mononuclear phagocytic system are immune cells that have the capacity to engulf and destroy numerous potentially pathogenic materials and organisms within the body. These cells are found in almost every site of the body, save a few 'immune privileged' sites (e.g. eyes, fetus, and testes). Such cells help with non-specific (innate) immune defenses as well as help initiate specific (adaptive) immune responses, thus they play a critical role bridging the gap between innate and adaptive immune responses. Our core capabilities combine the use of lipids as active pharmaceutical ingredients (API) and the use of lipids in "cochleate-shaped" lipid-crystal nano-particle drug delivery vehicles. Therapeutic applications of our proprietary delivery technology were 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 to focus on the delivery of a wide range of therapeutic treatments, in particular those in the oligonucleotide space (siRNA, DNA, antisense DNA, 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 addressable with our LNC platform delivery technology.

Our LNC technology is currently being used to encapsulate potent anti-infective drugs in tiny lipid-crystals which are selectively picked up by cells in the mononuclear phagocytic system, such as macrophages, and transported to infected cells. These tiny lipid crystals are referred to as "cochleates." Cochleates have a multilayer crystalline, spiral structure with no internal aqueous space. The structure is formed when a series of solid lipid sheets roll up and engulf drug molecules in between the sheets, a proprietary process referred to as "encochleation". The result is a lipid-crystal encochleated drug formulation made up of nano-sized particles. We believe our cochleate delivery technology provides an effective delivery mechanism without chemically bonding or otherwise altering the drug. Because the medications are locked in the particles, we believe the exposure to sensitive organs will be reduced, potentially resulting in reduced toxic effects. In summary, we believe this unique technology offers (1) targeted delivery, (2) decreased toxic effects, and (3) oral formulation (even for IV-only medications).

Multi-organ Protection: The key innovation of our cochleate delivery technology is our ability to package medication inside lipid-crystal particles without leaking. Because of their crystal nature, these particles are truly solid and hold on tightly to their medication pay-load. This is where the cochleate 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 strongly differentiates our cochleate delivery technology from other drug-delivery approaches.

Targeted Delivery: The size of our individual cochleate lipid-crystals 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 bacteria. Our body produces several cell-types that are designed to remove viruses and bacteria from our system. These cell types, such as macrophages, are part of our immune system and "swallow" the bacteria and viruses they encounter in order to protect us from infections. Because of the size our lipid-crystal cochleate particles and the phospholipid surface structure (the cell membranes of bacteria are also made up from phospholipids), macrophages tend to absorb these cochleate particles very well.

Oral Formulation: Many drugs that are currently on the market are only effective in treating diseases when administered via IV. For example, many anti-infective drugs must be administered via IV 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 oral formulation. We believe that the unique cochleate crystal-structure in our platform technology protects the drug from degradation when it passes through the gastrointestinal (GI) tract and that its lipid surface features facilitate the particle to be absorbed into the blood stream. The potential application of our cochleate delivery technology for the delivery of injectable medications offers significant clinical and commercial value if successfully demonstrated in human clinical trials. It is our intent to further validate the LNC Platform technology in our planned cryptococcal meningitis study.

Our cochleate lipid-crystal nano-particle 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. Besides 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 be the result of transport of our drug-loaded cochleates by macrophages and other immune-cells. For example, in a mouse model of invasive candidiasis, comparing orally administered MAT2203 to injected amphotericin B deoxycholate (original drug Fungizone), we observed amphotericin B levels above the minimal inhibitory concentration inside infected organs on day 1 with MAT2203 treatment while such levels were not reached with the injected original amphotericin-deoxycholate product until 3-4 days of treatment. Such kinetics have been seen before with other medications, such as macrolide antibiotics (e.g. azithromycin). It appears from our data that the kinetics of cochleate delivery has similarities to the kinetics of macrolide antibiotics. We expect that additional preclinical and clinical work on the kinetics of our cochleate products will further elucidate the mechanism of cochleate delivery to the site of infection or inflammation.

Strategic Collaborations Using LNC 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. Leveraging our cochleate delivery technology, we believe we can develop a robust pipeline of product candidates, either internally or through robust strategic partnerships with pharmaceutical and biotech companies. We have tested a range of pharmaceutical compounds reformulated by our cochleate delivery technology in proof-of-concept animal studies, including oligonucleotides (mRNA, siRNA, DNA plasmids), vaccines, anti-inflammatory agents, NSAIDs and atovaquone. By way of example, in 2016 we received a patent issuance related to LNC compositions directed against expressions of proteins. The allowed patent claims cover our proprietary methods related to the composition and the formation of encochleated siRNA for potential use as therapy for regulating gene expression. 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.

We continue to actively collaborate with the NIH on a number of therapeutic fronts to further expand the generation of data to support broad use of our LNC platform technology across broad therapeutic treatment modalities. In July 2018, we announced a research collaboration with the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health (NIH) focused on the development of a novel therapy for the treatment of human immunodeficiency virus (HIV) combining targeted antisense oligonucleotides (ASO) and our LNC delivery technology. The goal of this collaboration is to leverage the unique attributes of our LNC technology to safely, effectively and efficiently deliver ASO intracellularly to inhibit Trans-Activator of Transcription (Tat)/viral mRNA translation. Tat is a contributing factor in three major aspects of HIV infection post treatment with antiretroviral therapy (ART): viral replication/latency, chronic inflammation and neurological complications. Tat is a key regulatory protein not specifically targeted by currently available ART. *In vitro* and *in vivo* studies will be conducted to determine optimal structures for incorporating ASOs into the LNC technology platform, delivery into target cells and the effective inhibition of Tat and/or viral replication while monitoring Tat-induced cytotoxicity.

In January 2019 we announced a research evaluation with an undisclosed top global pharmaceutical company aimed to evaluate synergistic effects of our lipid-nano-crystal ("LNC") platform delivery technology with our partner's nucleic acid polymer technology. Formulations will be developed using our LNC 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.

Exclusive License Agreement with Rutgers University

Through our acquisition of Aquarius Biotechnologies Inc., we acquired a license from Rutgers University for the cochleate 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 MAT9001

We have sought patent protection in the United States and internationally for our MAT9001 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 MAT9001 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 MAT9001 through 2033. In addition, we have nineteen additional patent applications across four patent families covering the oil composition for MAT9001, other omega-3 fatty acid compositions, as well as formulations of MAT9001 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 MAT9001 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 Cochleate Delivery Technology Platform 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 nano-crystal 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 11 pending applications and 22 issued U.S. and foreign patents, including 15 patents issued within the last 3 years, which extends patent protection until at least 2033. In addition, we have 28 Matinas-owned pending patent applications filed both in the United States and in foreign jurisdictions within the past 3 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 2037. This patent portfolio covers our cochleate delivery system which covers a broad spectrum of technology, including amphotericin B cochleates, geodate cochleates, methods of delivering nutrients or biologically relevant molecules to a host using cochleates, cochleate vaccine compositions and protein-lipid vesicles, small interfering RNA cochleates, mRNA cochleates methods of enhancing the encochleation of hydrophilic molecules and cochleates made with low purity soy phosphatidylserine.

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 technology platform as well as the manufacture of certain intermediates utilized in MAT9001, 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.

MAT9001

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 severe hypertriglyceridemia, 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 severe hypertriglyceridemia 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 severe hypertriglyceridemia.

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 severe hypertriglyceridemia. Epanova was developed by Omthera Pharmaceuticals, Inc., and is now owned by AstraZeneca Pharmaceuticals LP (AstraZeneca). Also, in April 2014, Omtryg, another omega-3-acid fatty acid composition developed by Trygg Pharma AS, received FDA approval for severe hypertriglyceridemia. Neither Epanova nor Omtryg have been commercially launched, but could launch at any time. Each of these competitors, other than Trygg, has greater resources than we do, including financial, product development, marketing, personnel and other resources.

We are also aware of other pharmaceutical companies that are developing products that, if successfully developed, approved and marketed, would compete with MAT9001. Acasti Pharma, or Acasti, a subsidiary of Neptune Technologies & Bioresources Inc., announced in December 2015 that it intends to pursue a regulatory pathway under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA, for its omega-3 prescription drug candidate, CaPre® (omega-3 phospholipid), derived from krill oil, for the treatment of hypertriglyceridemia.

Akcea Therapeutics/Ionis Pharmaceuticals (formerly Isis Pharmaceuticals), or Akcea/Ionis, in August 2018 announced the receipt of a complete response letter from the FDA for WAYLIVRA™ (volanesorsen), a drug candidate administered through weekly subcutaneous injections, for the treatment of familial chylomicronemia syndrome (FCS). Akcea will continue to work with the FDA on the path forward for Waylivra for the treatment of FCS. Waylivra continues to be developed for the treatment of familial partial lipodystrophy (FPL).

In June 2018, Gemphire Therapeutics announced positive topline results from a Phase 2b trial (INDIGO-1) of its drug candidate, gemcabene, in patients with severe hypertriglyceridemia. Gemcabene is an oral, once-daily pill for a number of hypercholesterolemic populations and severe hypertriglyceridemia.

Zydus Cadila has a Phase 2 development program for its lead molecule, Saroglitazar, in various indications, including severe hypertriglyceridemia in the United States. In August 2018, the Company announced that it had suspended the Phase 2 trial in the severe hypertriglyceridemia indication due to study enrollment issues, while it continues development activities in other indications. The product is approved in India under the name Lipaglyn® for the treatment of hypertriglyceridemia and diabetic dyslipidemia. We are also aware that bezafibrate has been licensed by Intercept Pharmaceuticals to be further developed and potentially launched in the United States market.

MAT2203

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 any other development candidate we may pursue in the future using our proprietary cochleate drug delivery technology platform, 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 candidemia 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.), CD101 (being developed by Cidara Therapeutics, Inc.) and certain products being developed by Viamet Pharmaceuticals Holdings, LLC, Vical Incorporated and F2G, Ltd.

Manufacturing

We currently contract with one third party manufacturer to supply us with certain of the intermediates used in MAT9001 and a second manufacturer to formulate a third intermediate and supply us with the final drug form. We have a third manufacturer which fills and provides our final MAT9001 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 MAT9001 drug product as we advance MAT9001 further into clinical development.

We currently lease and operate in-house manufacturing capabilities for our lead LNC platform delivery technology product candidate, MAT2203, 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, 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 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.

There are a number of potential third-party suppliers for amphotericin B, the generic active pharmaceutical ingredients in our lead clinical stage product candidate – MAT2203. Although to date we have not entered into formal supply agreements to secure sufficient supply of amphotericin B to support our clinical programs for MAT2203, we believe we will be able to secure supply of amphotericin B to support our clinical programs for MAT2203 and from one or more third-party suppliers. As we move through development for our product candidate, 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 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 larger number of trial participants, may be 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 after September 27, 2007; 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 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 treatserious 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, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, ("HIPAA"). 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.

Employees

As of March 15, 2019, we had 15 full-time employees.

Research and Development

For the years ended December 31, 2018 and 2017, we incurred approximately $6.8 million and $9.0 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.

Implications of Being an Emerging Growth Company

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012. We will remain an emerging growth company until December 31, 2019, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1.07 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period.

For as long as we remain an "emerging growth company," we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and financial statements in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote to approve executive compensation and shareholder approval of any golden parachute payments not previously approved. We will take advantage of these reporting exemptions until we are no longer an "emerging growth company."

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, and Matinas BioPharma Nanotechnologies, Inc., a Delaware corporation. Nereus BioPharma LLC, a Delaware limited liability company (and Matinas BioPharma's predecessor) was formed on August 12, 2011. On February 29, 2012, Nereus BioPharma LLC converted from a limited liability company to a corporation and changed its name to Matinas BioPharma, Inc. In July 2013, Matinas BioPharma, Inc. merged with and into a wholly-owned subsidiary of ours, thereby becoming a wholly owned subsidiary of ours. On January 29, 2015, we acquired Aquarius Biotechnologies Inc. which was subsequently renamed Matinas BioPharma Nanotechnologies, 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.

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 $14.4 million and $15.5 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $65.9 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 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 preclinical and clinical studies of MAT9001, our lead product candidate;
- 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 MAT9001, our lead product candidate, as well as the anticipated Phase 2 clinical trial of MAT2203 in cryptococcal meningitis, 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 and cash equivalents, including restricted cash, of approximately $13.0 million as of December 31, 2018, plus an additional $30.5 million in net proceeds from a public offering of our common stock in March 2019, will enable us to fund our operating expenses and capital expenditure requirements through 2020. 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 MAT9001;
- 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 cochleate delivery technology platform, and any preclinical or clinical work done to further validate our cochleate 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. 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, 2018, we had outstanding options to purchase an aggregate of 13,456,796 shares of our common stock at a weighted average exercise price of $1.13 per share and warrants to purchase an aggregate of 5,799,429 shares of our common stock at a weighted average exercise price of $0.61 per share. In addition, as of December 31, 2018, we had 1,467,858 million shares of Series A Preferred Stock outstanding and 4,819 shares of Series B Preferred Stock outstanding. Each share of Series A Preferred Stock may be converted into 10 shares of common stock upon the earlier of (i) request of the holder (ii) certain fundamental transactions, (iii) July 29, 2019, and (iv) FDA or EMA regulatory approval for either of MAT2203 or MAT2501, and 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 cochleate delivery technology and (ii) 1,500,000 shares issuable upon FDA approval of the first NDA submitted by us for a product utilizing the cochleate 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, as a young business, 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 completed a PK/PD study of MAT9001 head to head vs. Vascepa in 2015. We recently 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 MAT9001, MAT2203, 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 MAT9001, MAT2203 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 MAT9001. 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 partially 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.

Clinical drug development involves a lengthy and expensive process with uncertain outcomes that may lead to delayed timelines and increased cost, and may prevent us from being able to complete clinical trials.

Clinical testing is expensive, can take many years to complete, and its outcome is inherently uncertain. The results of preclinical and clinical studies of our product candidates may not be predictive of the results of later-stage clinical trials. For example, the positive results generated to date in Phase 2 clinical studies for MAT9001 do not ensure that our Phase 3 clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies, and we cannot be certain that we will not face similar setbacks.

We cannot be certain that future clinical trials for MAT9001, MAT2203 or any of our other product candidates, will begin on time, not need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all, or that any interim analyses with respect to such trials will be completed on schedule or support continued clinical development of the associated product candidate.

We could also encounter delays if a clinical trial is suspended or terminated by us upon recommendation of the data monitoring committee for such trial, by the IRBs of the institutions in which such trials are being conducted, or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions, or lack of adequate funding to continue the clinical trial.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate revenue from the sale of any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval processes, and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may significantly harm our business, financial condition and prospects significantly.

Delays in the commencement, enrollment and completion of our clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for MAT9001 and our other product candidates.

Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of our product candidates. The commencement, enrollment and completion of clinical trials can be delayed for a variety of reasons, including:

- inability to reach agreements on acceptable terms with prospective contract research organizations (CROs) and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inability to maintain necessary supplies of study drug and comparator to maintain predicted enrollment rates at clinical trial sites;
- regulatory objections to commencing a clinical trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- inability to obtain institutional review board approval, including that within the NIH, to conduct a clinical trial;
- difficulty recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indication as our product candidates;
- inability to retain subjects in clinical trials due to the treatment protocol, personal issues, side effects from the therapy or lack of efficacy; and
- difficulty in importing and exporting clinical trial materials and study samples.

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 technology needed for the clinical development our MAT2203 product candidate and rely exclusively on third party manufacturers for the manufacture of MAT9001. If we do not develop a long term in-house manufacturing capability for the cochleates needed for our 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, 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.

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 MAT9001, MAT2203 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 MAT9001, MAT2203 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 MAT9001, MAT2203 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 MAT9001, MAT2203, 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 MAT9001, MAT2203 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 MAT9001, MAT2203 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 MAT9001, MAT2203 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 MAT9001 or MAT2203 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 MAT9001 and MAT2203 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, 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 MAT9001 for the treatment of severe hypertriglyceridemia. Although our interactions with the FDA have encouraged our efforts to continue to develop MAT9001 for severe hypertriglyceridemia, there is no assurance that we will satisfy the FDA's requirements for approval in this indication. Likewise, we intend to rely on the history of efficacy of amphotericin B, and anticipate meeting with the FDA in the first half of 2019 to discuss our development plans for MAT2203.The timelines for filing and review of our NDAs for MAT9001 and MAT2203 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 MAT9001 for severe hypertriglyceridemia, and the FDA may not approve our NDA based on their review of the submitted data. If omega-3 fatty acids-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 MAT9001, 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 candidate.

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 MAT9001, MAT2203 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 MAT9001, MAT2203 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 MAT9001, MAT2203 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 MAT9001, MAT2203 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 MAT9001, MAT2203 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.

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 MAT9001, MAT2203 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.

Changes in health care law and implementing regulations, including government restrictions on pricing and reimbursement, as well as health care policy and other health care payor cost-containment initiatives, may have a material adverse effect on us.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system and efforts to control health care costs, including drug prices, that could have a significant negative impact on our business, including preventing, limiting or delay regulatory approval of our drug candidates and reducing the sales and profits derived from our products once they are approved.

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 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 ACA, including the potential for further amendments to the ACA and legal challenges to or efforts to repeal the ACA.

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.

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 MAT9001, MAT2203 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, which exposes us to the risk of reliance on the performance of third parties.

In conducting our research and development activities for MAT2203, 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. 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 MAT9001, MAT2203 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 MAT9001, and MAT2203 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 MAT2203, MAT9001 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 MAT9001, MAT2203 and our other product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance of MAT9001, MAT2203 or any other product candidates that we may develop. If there is not sufficient reimbursement for our future products, it is less likely that such products will be widely used.

Market acceptance and sales of MAT9001, MAT2203 or any other product candidates for which we obtain regulatory approval will depend on reimbursement policies and may be affected by future healthcare reform measures in both the United States and foreign jurisdictions. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which products they will cover and establish payment levels. In addition, government authorities and these third-party payors are increasingly attempting to contain health care costs by demanding price discounts or rebates and limiting both the types and variety of products that they will cover and the amounts that they will pay for these products. In addition, we might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to such payors' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources.

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 MAT9001, MAT2203 or any other product candidates that we develop. 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 MAT9001, MAT2203 or any other product candidates that we develop.

MAT9001 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, MAT9001, if approved, would be subject to competition from products for which no prescription is required.

If approved by the regulatory authorities, MAT9001 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 MAT9001 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 MAT9001 as superior. To the extent the price of MAT9001 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 MAT9001 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 MAT9001

Unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives could harm our business.

There is increasing pressure on biotechnology companies to reduce healthcare costs. In the U.S., these pressures come from a variety of sources, such as managed care groups, institutional, government purchasers and government leaders. For example, President Trump has indicated support for possible new measures related to drug pricing. Increased purchasing power of entities that negotiate on behalf of federal healthcare programs and private sector beneficiaries could increase pricing pressures in the future. Such pressures may also increase the risk of litigation or investigation by the government regarding pricing calculations. The biotechnology industry will likely face greater regulation and political and legal action in the future.

The regulations that govern marketing approvals, pricing and reimbursement for new therapeutic products vary widely from country to country. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country.

Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval. Adverse pricing limitations prior to approval will also adversely affect us by reducing our commercial potential. Our ability to commercialize any products successfully also will depend in part on the extent to which reimbursement for these products and related treatments becomes available from government health administration authorities, private health insurers and other organizations.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and these third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with products administered under the supervision of a physician. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

There may be significant delays in obtaining reimbursement for approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or regulatory authorities in other countries. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Payment 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 and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government funded and private payors for new products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We are, and will be, completely dependent on third parties to manufacture MAT9001, and our commercialization of MAT9001 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 MAT9001 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 MAT9001 for use in our clinical trials or for commercial product, if any. In addition, we do not have the capability to encapsulate MAT9001 as a finished drug product for commercial distribution. As a result, we will rely on contract manufacturers throughout the development process and then if and when MAT9001 is 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 MAT9001 on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture MAT9001 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 MAT9001. 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 MAT9001 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 MAT9001, 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 MAT9001, 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 MAT9001.

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 MAT9001 product or should cease doing business with us, we could experience significant interruptions in the supply of MAT9001 or may not be able to create a supply of MAT9001 at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of MAT9001 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 MAT9001 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 the supply of MAT9001 if we decided to transfer the manufacture of MAT9001 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 MAT9001, 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 MAT9001 over time. If the commercial-scale manufacturing costs of MAT9001 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.

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 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 cochleate delivery technology, including our lead anti-infective product candidate, MAT2203. 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 cochleate delivery technology, including our lead anti-infective product candidate.

If we discontinue development of the cochleate 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' cochleate 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 cochleate delivery technology (as conclusively demonstrated by our omission of the cochleate 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 cochleate 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 cochleate 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 22 issued patents relating to our cochleate delivery technology, as well as pending patent applications for our cochleate 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 MAT9001, MAT2203 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 MAT9001 or MAT2203 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 MAT9001 or MAT2203 from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to MAT9001 or MAT2203 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, MAT9001, MAT2203, or 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 MAT9001, MAT2203 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.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is commonplace in our industry, we employ individuals who were previously employed at or retained by other pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non-competition or non-solicitation obligations) or claims that our employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

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

We may seek orphan drug designation for MAT2203 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 and the prevention of invasive fungal infections due to immunosuppressive therapy 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 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.

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 fifteen employees. 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, 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 MAT9001, MAT2203 or any future product candidates and will face an even greater risk if we commercialize MAT9001, MAT2203 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 MAT9001 or MAT2203. 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 MAT9001, MAT2203 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 outstanding 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 outstanding Series A Preferred Stock, we may be 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 2020, 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 Series A Preferred Stock are entitled to receive cumulative dividends at the rate per share of 8% per annum, payable in shares of our common stock, which annual dividend will accumulate until such time as the shares of Series A Preferred Stock are converted, at which time the accumulated dividend will be satisfied by delivery of shares of common stock at a price per share of common stock equal to the conversion price of the Series A Preferred Stock then in effect (currently $0.50 per share). The Series A Preferred Stock will automatically convert at the conversion price in effect on July 29, 2019, unless such shares are converted earlier in accordance with the terms of the Certificate of Designations for the Series A Preferred Stock.

Holders of our Series B Preferred Stock will be 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 Stock then held by the holder on June 19, 2019, (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 June 19, 2020 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 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.

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 A 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.

Our common stock was listed on the NYSE American under the symbol "MTNB" on March 2, 2017. Prior to March 2, 2017, our common stock was available for quotation on the OTCQB under the symbol "MTNB." 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. From January 1, 2016 through March 15, 2019, the market price of our common stock has fluctuated from a high of $3.99 per share in the first quarter of 2017 to a low of $0.35 per share in the third quarter of 2018. 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.

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

Although our common stock is listed on the NYSE, the market for our shares has demonstrated varying levels of trading activity. Furthermore, the current level of trading may not be sustained in the future. The lack of an active market for our common stock may impair investors' ability to sell their shares at the time they wish to sell them or at a price that they consider reasonable, may reduce the fair market value of their shares and may impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire additional intellectual property assets by using our shares as consideration.

We do not anticipate paying dividends on our common stock and, accordingly, stockholders must rely on stock appreciation for any return on their investment.

We have never declared or paid cash dividends on our common stock and do not expect to do so in the foreseeable future. The declaration of dividends is subject to the discretion of our board of directors and limitations under applicable law, and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our board of directors. You should not rely on an investment in our company if you require dividend income from your investment in our company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our common stock, which is uncertain and unpredictable. There is no guarantee that our common stock will appreciate in value.

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.

We are an "emerging growth company," and we intend to take advantage of reduced disclosure requirements applicable to "emerging growth companies," which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and, for as long as we continue to be an "emerging growth company," we intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies but not to "emerging growth companies," including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an "emerging growth company" until December 31, 2019, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period. We cannot predict if investors will find our common stock less attractive if we choose to continue to rely on these exemptions. If some investors find our common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

We are incurring significantly increased costs and devote substantial management time as a result of operating as a public company, which costs may increase after we are no longer an "emerging growth company."

As a public company, we are incurring significant legal, accounting and other expenses. For example, we are required to comply with certain of the requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the SEC, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Compliance with these requirements have resulted in increased legal and financial compliance costs. In addition, our management and other personnel must divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we are incurring significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act.

However, for as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We intend to take advantage of these reporting exemptions until we are no longer an "emerging growth company."

Under the JOBS Act, "emerging growth companies" can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

After we are no longer an "emerging growth company" we expect to incur additional management time and cost to comply with the more stringent reporting requirements applicable to companies that are deemed accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

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.

We have identified material weaknesses in our internal control over financial reporting. If we are not able to remediate these material weaknesses and otherwise 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, 2018, our internal control over financial reporting was not effective, as management identified deficiencies in internal control over financial reporting that were determined to be material weaknesses.

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.

Furthermore, we did not maintain a sufficient complement of accounting personnel with a sufficient knowledge and training in the application of U.S. GAAP. This deficiency led to the failure to maintain, document and apply appropriate account standards in the areas of income tax provisions, convertible equity securities, and stock based compensation.

If our steps are insufficient to successfully remediate the material weaknesses 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. For as long as we are an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an "emerging growth company" until December 31, 2019, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed $1 billion, (ii) the date that we become a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. 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 error 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 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. The Tax Act, among other things, imposes significant additional limitations on the deductibility of interest and limits net operating loss (NOL) deductions.

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. 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

From July 21, 2014 to March 1, 2017, our common stock commenced quotation on the OTCQB under the symbol "MTNB". The following table sets forth, for the periods January 1, 2017 until December 31, 2018, the reported high and low bid quotations per share for our common stock based on information provided by the OTC Market Group, Inc. Such OTCQB over-the-counter market quotations reflect inter-dealer prices, without markup, markdown or commissions and, particularly because our common stock is traded infrequently, may not necessarily represent actual transactions or a liquid trading market. Our common stock was listed on NYSE American effective March 2, 2017. The following table sets forth, for the periods March 2, 2017 until December 31, 2018, the reported high and low sales price per share for our common stock based on information provided by the NYSE American.

	Fiscal Year 2017	
	High	Low
First Quarter	$ 3.99	$ 1.39
Second Quarter	$ 3.20	$ 1.40
Third Quarter	$ 1.80	$ 1.01
Fourth Quarter	$ 1.60	$ 1.02

	Fiscal Year 2018	
	High	Low
First Quarter	$ 1.32	$ 0.77
Second Quarter	$ 0.74	$ 0.42
Third Quarter	$ 0.92	$ 0.35
Fourth Quarter	$ 1.11	$ 0.53

Holders

On March 29, 2019, the closing sale price of our common stock, as reported by the NYSE American, was $1.12 per share andwe had approximately 126 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.

Equity Compensation Information

The following table summarizes information about our equity compensation plans as of December 31, 2018.

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)	13,456,796	$ 1.13	2,374,863
Equity compensation plans not approved by stockholders	—	—	—
Total	13,456,796	$ 1.13	2,374,863

(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 4,531,507 shares were automatically made available for issuance on the first trading day of 2018, which represents 4% of the number of shares outstanding on December 31, 2018; these shares are excluded from this calculation.

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, 2018.

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 a clinical-stage biopharmaceutical company focused on creating value through (i) the streamlined development under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA of our lead product candidate, MAT9001, a highly purified, prescription-only omega-3 free fatty acid formulation specifically designed for the treatment of cardiovascular and metabolic conditions and (ii) the application of our lipid nano-crystal (LNC) platform delivery technology to solve complex challenges relating to the delivery of small molecules, gene therapies, vaccines, proteins and peptides, including MAT2203, our lead product candidate based on the LNC technology. In general, the development timeline for a 505(b)(2) New Drug Application, or NDA, is shorter and less expensive than an NDA developed under Section 505(b)(1) for new chemical entities that have never been approved in the United States. Based upon MAT9001's unique mixture of highly purified omega-3 free fatty acids and our observations of MAT9001's enhanced bioavailability and potency as compared to Amarin Corporation's Vascepa® (icosapent ethyl) in our initial head-to-head pharmacokinetic (PK) and pharmacodynamic (PD), or PK/PD, clinical study, we believe that the results of our forthcoming targeted clinical development activities and related clinical investigations may yield an improved therapeutic profile compared to currently-existing therapies.

We are focused on creating value through the streamlined and strategic development of MAT9001 for the treatment of cardiovascular and metabolic conditions and the application of our LNC platform delivery technology to solve complex challenges relating to the delivery of small molecules, gene therapies, proteins/peptides, and vaccines. Key elements of our strategy include:

- Strategically advancing MAT9001 into clinical development toward an initial indication for the treatment of severe hypertriglyceridemia (≥500 mg/dL) (SHTG) with the goal of creating additional data further demonstrating the differentiation of MAT9001 from other prescription omega-3 drugs being used to treat a mixed dyslipidemic patient population in a rapidly emerging and expanding omega-3 market.

- Expanding application of our lipid nano-crystal (LNC) delivery platform into the gene therapy space through collaborations with sophisticated and well-resourced biotech and pharmaceutical companies in innovative areas of medicine.

- Driving MAT2203 to efficacy data in the treatment of cryptococcal meningitis, an area of significant unmet medical need, with the non-dilutive financial support of the NIH

We have incurred losses for each period from inception. Our net loss was approximately $14.1 million and $15.5 million for the fiscal years ended December 31, 2018 and 2017, 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 year ended December 31, 2018 and 2017, we generated approximately $.1 million and $.1 million, respectively, in contract research revenues, resulting from a grant with the Cystic Fibroses Foundation. 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. The Company has adopted ASC 606 as of January 1, 2018. For the year ended December, 31, 2018, there were no changes to our opening balances upon the adoption of ASC 606 and the amounts which would have been reported under the standards in effect prior to adoption.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of product candidates and advancement of our LNC delivery technology platform, 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 National Institutes of Health (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, 2018 and 2017. 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)	
	2018	2017
Direct research and development expenses:		
Manufacturing process development	$ 443	$ 361
Preclinical trials	1,240	923
Clinical development	624	3,244
Regulatory	163	282
Internal staffing, overhead and other	4,317	4,200
Total research & development	$ 6,787	$ 9,010

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 2019, we will be focused on advancing our lead product candidate, MAT9001 into clinical development toward an initial indication for the treatment of severe hypertriglyceridemia, expanding application of our LNC delivery platform through collaborations with third parties, and driving MAT2203 to efficacy data in the treatment of cryptococcal meningitis.

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 2019 due to the increased expenses related to our status as a publicly traded company, including expenses in support of compliance with the requirements of Section 404 of the Sarbanes Oxley Act as well as investor relations, protection of our intellectual property 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 $0.6 million for the year ended December 31, 2017. We did not recognize income from the sale of NOLs for the year ended December 31, 2018.

Other Income, net

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

Application of Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Annual Report. We believe the following accounting procedures to be most critical to the judgments and estimates used in the preparation of our financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses, particularly for product development costs. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments as necessary. Examples of estimated accrued research and development expenses include:

- fees paid to contractors in connection with the development of manufacturing processes for products in development;
- fees paid to CROs in connection with preclinical and clinical development activities;
- fees paid to contractors in connection with preparation of regulatory submissions; and
- fees paid to vendors related to product manufacturing, development and distribution of clinical study supplies.

We base our expenses related to pre-clinical and human studies on our estimates of the services received and efforts expended pursuant to contracts with multiple development contractors that conduct and manage development work and studies on our 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 our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts may depend on factors such as the successful enrollment of subjects and the completion of specific study milestones. In accruing service fees, we will estimate the time period over which services will be performed, the completion of certain tasks, enrollment of subjects, study center activation 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 our estimate, we will adjust the accrual or prepayment accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low in any particular period. Based on limited historical experience, actual results have not been materially different from our estimates.

Identifiable Intangible Assets

Identifiable intangible assets are measured at their respective fair values and are not amortized until commercialization. Once commercialization occurs, these intangible assets will be amortized over their estimated useful lives. The fair values assigned to our intangible assets are based upon reasonable estimates and assumptions given available facts and circumstances. Unanticipated events or circumstances may occur that may require us to review the assets for impairment. Events or circumstances that may require an impairment assessment include negative clinical trial results, material delays in our development program or sustained decline in market capitalization.

Indefinite-lived intangible assets are not subject to periodic amortization. Rather, indefinite-lived intangibles are reviewed for impairment by applying a fair value based test on an annual basis or more frequently if events or circumstances indicate impairment may have occurred. Events or circumstances that may require an interim impairment assessment are consistent with those described below. We perform our annual impairment test in December of each year.

Research and Development Expenses

Research and development expenses are charged to operations as they are incurred.

Stock-Based Compensation

Option Grants

We account for all share-based compensation payments issued to employees, directors, and non-employees using an option pricing model for estimating fair value. Accordingly, share-based compensation expense is measured based on the estimated fair value of the awards on the date of grant. We recognize compensation expense for the portion of the award that is ultimately expected to vest over the period during which the recipient renders the required services to us using the straight-line single option method. In accordance with authoritative guidance, we re-measure the fair value of non-employee share-based awards as the awards vest, and recognize the resulting value, if any, as expense during the period the related services are rendered. The Company accounts for forfeitures of all share-based awards as they occur.

Significant Factors, Assumptions and Methodologies Used in Determining Fair Value

We apply the fair value recognition provisions of ASC Topic 718, *Compensation-Stock Compensation*, which we refer to as ASC 718. We recognize share-based compensation expense ratably over the requisite service period, which in most cases is the vesting period of the award. Calculating the fair value of share-based awards requires that we make highly subjective assumptions.

We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. As a publicly-held company, we utilized our historical data to estimate expected stock price volatility.

We use the simplified method as prescribed by the Securities and Exchange Commission Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term of stock option grants to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees.

We recognize compensation expense for stock option 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 options granted subject to a consulting agreement, whereby the option vesting period and the service period defined pursuant to the terms of the consulting agreement may be different. Stock options issued to consultants are revalued quarterly until fully vested, with any change in fair value expensed. For awards subject to performance conditions, the Company recognizes stock-based compensation expense using the accelerated attribution recognition method when it is probable that the performance condition will be achieved. The following range of assumptions were used to value options granted for the years ended December 31, 2018 and 2017 and to re-measure stock options issued to consultants.

	For the Year Ended December 31,	
	2018	2017
Volatility	105.85% - 111.31%	67.8% - 109.63%
Risk-free interest rate	2.29% - 3.08%	1.89% - 2.37%
Dividend yield	0.0%	0.0%
Expected life	6.0 years	6.0 years

The expected stock price volatility assumption was determined by examining the Company's historical volatility. We will continue to analyze our expected term assumptions as more historical data for our common stock becomes available. The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of our stock options. The expected dividend assumption is based on our history and expectation of dividend payouts.

We have never paid dividends on our common stock and do not anticipate paying dividends on our common stock in the foreseeable future. Accordingly, we have assumed no dividend yield for purposes of estimating the fair value of our share-based compensation.

Stock-based compensation expense associated with stock options, restricted stock granted to employees and non-employees was approximately $3.8 million and $3.6 million for December 31, 2018 and 2017, respectively. As of December 31, 2018, we had approximately $3.0 million of total unrecognized share-based compensation expense, which we expect to recognize over a weighted-average remaining vesting period of approximately 2.2 years. In future periods, our share-based compensation expense is expected to increase as a result of recognizing our existing unrecognized share-based compensation for awards that will vest and as we issue additional share-based awards to attract and retain our employees.

The closing price of our stock (on the date of a grant) is used as an input in the measurement of stock-based compensation.

The 2013 Equity Compensation Plan, as amended, or the Plan, is the only active plan pursuant to which options to acquire common stock or restricted stock awards can be granted and are currently outstanding. As of December 31, 2018, there were 2.4 million shares of our common stock available for issuance under the Plan.

As of December 31, 2018, we had outstanding options to purchase an aggregate of approximately 13.5 million shares of our common stock with a weighted average exercise price of $1.13. At December 31, 2018, approximately 9.5 million options had vested at a weighted average exercise price of $1.17 per share. The computation of the aggregate intrinsic value is based upon the difference between the original exercise price of the options and our estimate of the deemed fair value of our common stock at December 31, 2018. The total intrinsic value of options outstanding and vested at December 31, 2018 was approximately $0.5 million.

Basic and Diluted Net Loss Per Share of common stock

We compute basic net loss per share of common stock by dividing net loss applicable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects stock options. We compute diluted net loss per share of common stock by dividing the net loss applicable to common stockholders by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects stock options outstanding during the period calculated in accordance with the treasury stock method, but such items are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between our basic and diluted net loss per share of common stock for the years ended December 31, 2018 and 2017.

Emerging Growth Company Status

Under Section 107(b) of the Jumpstart Our Business Startups Act of 2012, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Current Operating Trends

Our current research and development efforts are focused on developing MAT9001. Our research and development expenses consist of manufacturing work and the cost of drug ingredients 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 all of our research and development 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, 2018 and 2017

The following table summarizes our operating expenses for the years ended December 31, 2018 and 2017:

	Year Ended December 31,	
	2018	**2017**
	($ in thousands)	
Expenses:		
Research and development	$ 6,787	$ 9,010
General and administrative	7,979	7,642
Operating Expenses	$ 14,766	$ 16,652

Research and Development expenses. Research and Development (R&D) expense for the year ended December 31, 2018 was approximately $6.8 million, a decrease of approximately $2.2 million over the prior year. R&D expenses decreased mainly due to lower clinical development and compensation expenses partially offset by higher preclinical expenses and a full year of costs associated with operating the new laboratory & manufacturing facility.

General and Administrative expenses. General and administrative expense for the year ended December 31, 2018 was approximately $8.0 million, an increase of approximately $0.3 million over prior year. The increase in general and administrative expense was primarily due to higher compensation and insurance expense partially offset by lower professional fees.

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, 2018, we have raised a total of approximately $67.7 million in gross proceeds and $60.8 million, net, from sales of our equity securities.

As of December 31, 2018, we had cash and cash equivalents totaling $12.4 million.

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 27,272,727 shares to the public at a price of $1.10 per share. The Company generated net proceeds of approximately $28.2 million. 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. If the underwriters exercise the option in full, additional net proceeds of approximately $4.2 million will be generated. 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.

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.

2017 Controlled Equity Offering

We entered into a Controlled Equity Offering^{SM} Sales Agreement with Cantor Fitzgerald & Co. "Cantor", pursuant to which, subject to certain limited restrictions and daily sales limits, we may sell shares of common stock having an offering price of up to $30 million. Through December 31, 2018, we raised a net of approximately $10.4 million through this agreement.

2017 Warrant Tender Offer and Exercised Warrants

On January 13, 2017, we completed a tender offer to amend and exercise certain categories of existing warrants.

Pursuant to the Offer to Amend and Exercise, an aggregate of 30,966,350 Warrants were tendered by their holders. The gross cash proceeds from such exercises were approximately $13.5 million and the net cash proceeds after deducting warrant solicitation agent fees and other estimated offering expenses were approximately $12.7 million. Prior to the Offer to Amend and Exercise, we had 58,159,495 shares of common stock outstanding and warrants to purchase an aggregate of 40,255,234 shares of common stock. Immediately following the Offer to Amend and Exercise (after the effect of certain cash and cashless exercises), the Company issued in exchange for the warrants 29,666,782 common shares.

In addition, while no warrants were exercised in 2018, the Company received approximately $2.2 million in 2017 from the exercise of warrants.

Cash Flows

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

	Year Ended December 31 ($ in thousands)	
	2018	**2017**
Cash used in operating activities	$ (10,321)	$ (11,459)
Cash used in investing activities	(536)	(942)
Cash provided by financing activities	15,867	15,602
Net increase in cash and cash equivalents and restricted cash	$ 5,010	$ 3,201

Operating Activities

We have incurred significant costs in the area of research and development, including clinical, manufacturing, analytical, regulatory and other development costs. In addition, general and administrative expenses are incurred related to being a public company, personnel costs in the Finance and Executive area, as well as costs associated with legal, accounting and investor relation services. Net cash used in operating activities was approximately $10.3 million for the year ended December 31, 2018 and $11.5 million for the year ended December 31, 2017. Subject to our ability to raise additional capital, we expect that there will be a significant increase in cash used in our research and development activities during 2019 as we continue to move our product candidates and delivery platform forward in their development cycle, add R&D headcount and further establish our new laboratory and manufacturing facility.

Investing Activities

Approximately $0.6 million and $0.9 million of cash was used in investing activities for the years ended December 31, 2018 and 2017, respectively. The investments were primarily related our laboratory facility, which we will continue to invest in during 2019.

Financing Activities

Net cash provided by financing activities was $15.9 million for the year ended December 31, 2018. The cash provided by financing activities in 2018 was primarily due to the issuance of Series B Preferred Stock in June and sales of our common stock through the Controlled Equity Offering[SM].

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 MAT9001, our lead product candidate;
- 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.

We expect that our existing cash and cash equivalents, coupled with the approximately $30.5 million of net proceeds generated from the recently completed underwritten public offering of common stock, will be sufficient to fund our operating expenses and capital expenditures requirements through 2020.

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 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

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. The Company was obligated to provide an initial security deposit of $300,000 to obtain the office lease space. The deposit was subsequently reduced and is currently $50,000, which it will remain at for the balance of the lease term.

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 been reduced to $486,000. It can be further reduced by $100,000, $100,000 and $86,000 on each of the next three anniversaries of the rent commencement date, respectively, after which it will remain at $200,000 for the balance of the lease term.

Future minimum lease payments are as follows:

Year ending December 31,	Lease Commitments (in thousands)
2019	$ 713
2020	738
2021	663
2022	616
2023 and beyond	3,355
Total future minimum lease payments	$ 6,085

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

- On October 29, 2015, the Company agreed to provide funds in the amount of $132,405 per year under a CRADA to support NIH investigators to acquire technical, statistical and administrative support for research activities as well as to pay for supplies and travel expenses. The initial term of the CRADA was three years. The CRADA was amended and renewed on September 17, 2018, for an additional year without creating an additional funding commitment. On November 7, 2018, a second amendment was executed which created an additional funding commitment of $150,000, half of which was paid upon execution of the amendment. The balance is payable in May 2019.

- 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 encochleated drug products in patients with fungal, bacterial, or viral infections. The initial term of the CRADA was three years. The Company is in the final stages of amending and renewing the CRADA for an additional three years with an annual funding commitment of $200,000.

Through our acquisition of Aquarius, we 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 cochleate delivery technology. The Amended and Restated Exclusive License Agreement between Aquarius and Rutgers provides for, among other things, (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 $50,000 over the term of the license agreement.

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 MAT2203 or MAT2501.

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.

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 2, "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 and cash equivalents, all of which have maturities of one year or less. 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, 2018, 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 not effective at the reasonable assurance level as of December 31, 2018, due to the material weaknesses in our internal control over financial reporting, which are described below under "Management's Annual Report on Internal Control Over Financial Reporting." Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within time periods specified by the SEC's rules and forms, and that such information is accumulated and communicated to our management, including principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, but not absolute, assurance that the objectives of the disclosure controls and procedures are met. The design of any disclosure control and procedure also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

As a result of the material weaknesses identified, we performed additional analysis, substantive testing and other post-closing procedures intended to ensure that our consolidated financial statements were prepared in accordance with U.S. GAAP. Accordingly, management believes that the consolidated financial statements and related notes thereto included in this annual report on Form 10-K fairly present, in all material respects, the Company's financial condition, results of operations and cash flows for the period presented.

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, 2018, our internal control over financial reporting was not effective, as management identified deficiencies in internal control over financial reporting that were determined to be material weaknesses.

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.

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.

Furthermore, we did not maintain a sufficient complement of accounting personnel with sufficient knowledge and training in the application of U.S. GAAP. This deficiency led to the failure to maintain, document and apply appropriate account standards in the areas of income tax provisions, convertible equity securities, and stock based compensation.

The material weaknesses identified above could result in a misstatement to the aforementioned account balances and disclosures that would result in a material misstatement to the annual or interim consolidated financial statements would not be prevented or detected on a timely basis.

Because we are a non-accelerated filer, this annual report on Form 10-K does not include an attestation report of our independent registered public accounting firm.

Remediation Plan:

Management has initiated a remediation plan to address the control deficiencies that led to the material weaknesses. The remediation plan includes, but is not limited to:

- The enhancement of our financial reporting and operating policies and procedures, including design and implementation of additional controls over the initiation, processing and recording of transactions to ensure such transactions are complete, accurate and recorded in a timely manner.
- Hiring and training existing personnel on the application of accounting principles and adherence to newly adopted policies, procedures and controls.
- The Company also intends to retain the services of outside consultants, with relevant accounting experience, skills and knowledge in U.S. GAAP, working under the supervision and direction of the Company's management, to supplement the Company's accounting personnel.

Changes in Internal Control Over Financial Reporting:

Except for changes being implemented by the Company to address the material weakness identified above, there have been no changes in our internal control over financial reporting during the quarter ended December 31, 2018, that have materially affected, or are reasonably likely not to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Roelof Rongen stepped down as our Chief Executive Officer and a member of our board of directors effective March 15, 2018. We entered into a separation agreement with Mr. Rongen pursuant to which, among other things, Mr. Rongen is to receive 15 months in base salary as severance, payable in accordance with the Company's standard payroll practices over 15 months, Mr. Rongen agreed to provide transition services for a period of three months to assist in the transition process and Mr. Rongen was provided with an extension through three years after the separation date of the exercise period for his vested stock options. The separation agreement further provides for certain restrictions on sales of shares of our common stock held by Mr. Rongen. His departure as an officer and director of the Company was not due to a dispute or disagreement with the Company.

Our board of directors appointed Jerome D. Jabbour to serve as a member of our board of directors and to serve as our Chief Executive Officer. Mr. Jabbour is a co-founder of Matinas BioPharma. 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. 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) 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.

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	86	Chairman of the Board, Director
Jerome D. Jabbour	44	Chief Executive Officer and President, Director
James J. Ferguson	65	Chief Medical Officer
Keith A. Kucinski	49	Chief Financial Officer
Raphael J. Mannino	71	Chief Scientific Officer
Theresa Matkovits	51	Chief Development Officer
Patrick G. LePore	63	Vice Chairman of the Board, Director
Eric Ende	50	Director
James S. Scibetta	54	Director
Adam K. Stern	54	Director
Matthew Wikler	69	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) 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). Prior to Amgen Dr. Ferguson held a number of senior positions at AstraZeneca, 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 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.

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.

Theresa Matkovits, PhD has served as Chief Development officer since September 2018. She joined the Company after having most recently served as the Chief Operating Officer of ContraVir Pharmaceuticals (NASDAQ: CTRV). From 2013 to 2015, Dr. Matkovits served as Global Program Leader at NPS Pharmaceuticals. 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 Aradigm Corporation (NASDAQ: ARDM). Dr. Matkovits was recently appointed to serve on the Board of Appili Therapeutics. 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.

Directors

Herbert Conrad has served as our Chairman of the Board since July 2013 and as Chairman of the Board of Matinas BioPharma since October 2012. He also serves on the board of directors of Celldex Therapeutics, Inc. (NASDAQ: CLDX), Arbutus Biopharma Corporation (NASDAQ: ABUS) 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 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. Pharmasset was acquired by Gilead Sciences, Inc. for $11 billion in 2011. 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 G. LePore has served as Vice Chairman of the board of directors since September 2018. Mr. LePore served as Chairman, CEO and President of Par Pharmaceuticals, Inc. (NYSE: PRX) from September 2006 through November 2012. Mr. LePore transitioned to Chairman of the new company beginning in November 2012 and directed its eventual sale to Endo (NASDAQ: ENDP) in 2015. He began his career with Hoffmann La Roche and then founded Boron LePore and Associates, a medical communications company, which he took public in 1997 and was eventually sold to Cardinal Health in 2002. He is a Chairman of the Board of Directors of Lanett Company, Inc., member of the board of directors of PharMerica, and is a trustee of Villanova University. Mr. LePore earned his bachelor's degree from Villanova University and Master of Business Administration from Fairleigh Dickinson University.

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

Eric Ende has served as a member of 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.

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 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.

Adam Stern has served as a member of our board of directors since July 2013. Mr. Stern has been the head Private Equity Banking at Aegis Capital Corp. and CEO of SternAegis Ventures since 2012 and became one of our directors in July 2013. Prior to Aegis, from 1997 to November 2012, he was with Spencer Trask Ventures, Inc., most recently as a Senior Managing Director, where he managed the structured finance group focusing primarily on the technology and life science sectors. Mr. Stern held increasingly responsible positions from 1989 to 1997 with Josephthal & Co., Inc., members of the New York Stock Exchange, where he served as Senior Vice President and Managing Director of Private Equity Marketing. He has been a FINRA licensed securities broker since 1987 and a General Securities Principal since 1991. Mr. Stern is a director of Dance Biopharm, Inc. Mr. Stern is a former director of InVivo Therapeutics Holdings Corp. (OTCQB: NVIV), Organovo Holdings, Inc. (NYSE MKT: ONVO), LabStyle Innovations Corporation (OTCBB: DRIO) and PROLOR Biotech Ltd., which was sold to Opko Health, Inc. (NYSE: OPK) for approximately $600 million in 2013. Mr. Stern holds a Bachelor of Arts degree with honors from The University of South Florida in Tampa. We believe Mr. Stern is qualified to serve on our board of directors because of his extensive experience in corporate finance and experience in the life science industries.

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) 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) 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.

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 infectious diseases to provide counsel and support our growth. We have established a 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, and Eric Ende 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 five times during 2018. 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. Herbert Conrad, 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 once during 2018. 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 once during 2018. 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.

Section 16(a) Beneficial Ownership Reporting Compliance

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, 2018, all reports required to be filed under Section 16(a) were filed on a timely basis except that, due to administrative errors, each of Messrs. Conrad, Ende, Sciabetta and Wikler failed to timely file a Form 4 with respect to a grant of shares of common stock pursuant to the Company's 2013 Equity Compensation Plan, during the most recent fiscal year. This error was corrected in later filings.

Item 11. Executive Compensation

Summary Compensation Table – 2018

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 (other than the chief executive officer) who were serving as executive officers as of December 31, 2018 for services rendered in all capacities to us for the years ended December 31, 2018 and December 31, 2017 up to two additional individuals for whom disclosure would have been provided but for the fact that the individual was not serving as an executive officer of the Company as of December 31, 2018. These individuals are our named executive officers for 2018.

Name and Principal Position (1)	Year	Salary ($)	Bonus ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Jerome D. Jabbour	2018	366,458	84,000	804,269	-	1,254,727
Chief Executive Officer	2017	299,000	90,000	881,483	-	1,270,483
Raphael Mannino	2018	240,000	-	54,636	-	294,636
Chief Scientific Officer	2017	238,333	70,000	275,463	-	583,796
Roelof Rongen (2)	2018	183,333	-	-	200,000(3)	383,333
Former Chief Executive Officer	2017	383,333	160,000	1,322,224	-	1,865,557
Gary Gaglione (4)	2018	165,000	-	77,617	-	242,617
Former Chief Financial Officer	2017	218,333	50,000	275,463	-	543,796

(1)Amounts reflect the grant date fair value of option awards granted in 2018 and 2017 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. Rongen resigned on March 16, 2018.

(3)Amounts reflect severance payments made to Mr. Rongen in connection with his resignation.

(4)Mr. Gaglione retired on September 30, 2018.

Narrative Disclosure to Summary Compensation Table

Employment Agreements with Our Named Executive Officers

Jabbour

On September 3, 2013, we entered into an employment agreement with Mr. Jabbour for a period of three years, which was effective as of October 4, 2013. Under the terms of Mr. Jabbour's employment agreement, Mr. Jabbour received a signing bonus of $75,000 and a base salary of $275,000 per year. In addition, Mr. Jabbour is eligible to receive an annual bonus, which is targeted at 30% 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. If we terminate Mr. Jabbour's employment without cause or Mr. Jabbour resigns with good reason, we are required to pay him severance of up to nine months of his base salary plus benefits. In addition, the vesting of his outstanding options will be accelerated by six months upon such termination. 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 eighteen months of his base salary and his target annual bonus plus benefits. In addition, his outstanding options would vest in full upon such termination. Mr. Jabbour's employment agreement provides for an increase in base salary of $50,000 annually, upon the closing of an additional round of financing of at least $15 million and the initiation of the first Phase III study of MAT9001. 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.

Rongen

On March 27, 2017, the Company entered into an employment agreement with Mr. Rongen, with the terms effective as of March 1, 2017.Under the terms of Mr. Rongen's employment agreement, he received a base salary of $400,000 per year, subject to periodic adjustments as determined by our Board or Compensation Committee. In addition, Mr. Rongen was eligible to receive an annual bonus, targeted at 50% of his base salary based on his individual performance and our performance as a whole, as determined by our Board or Compensation Committee. If we terminated Mr. Rongen's employment without cause or Mr. Rongen resigned with good reason, subject to Mr. Rongen's execution and non-revocation of a release and compliance with any post-termination obligations owed to us, we were required to pay him severance of up to twelve months of his base salary, in effect on the date of termination, plus COBRA payments for twelve months. In addition, the vesting of his outstanding options, and any other outstanding equity held by him at the time of his termination, would be accelerated by six months upon such termination. If we terminated Mr. Rongen's employment without cause during the 24 month period immediately following a change of control or Mr. Rongen resigned with good reason during the 24 month period immediately following a change of control, subject to Mr. Rongen's execution and non-revocation of a release and compliance with any post-termination obligations owed to us, we were to pay him severance of up to eighteen months of his base salary, in effect on the date of termination, and his target annual bonus for the year in which the termination occurs plus COBRA payments for eighteen months. In addition, his outstanding options and any other outstanding equity held by him at the time of his termination, would vest in full upon such termination. Mr. Rongen is also subject to a customary non-disclosure agreement, pursuant to which Mr. Rongen has agreed to be subject to a non-compete and non-solicit covenant during for a period of eighteen months following termination of his employment.

We entered into a separation agreement dated March 15, 2018 with Mr. Rongen pursuant to which, among other things, Mr. Rongen will receive 15 months in base salary as severance, payable in accordance with the Company's standard payroll practices over 15 months, Mr. Rongen agreed to provide transition services to assist in the transition process and Mr. Rongen will be provided with an extension through two years after the separation date of the exercise period for his vested stock options. The separation agreement further provides for certain restrictions on sales of shares of our common stock held by Mr. Rongen.

Employment Agreement with Our Chief Financial Officer

On December 31, 2018, we entered into an employment agreement with Mr. Kucinski which was effective as of January 2, 2019. Under the terms of Mr. Kucinski's employment agreement, Mr. Kucinski receives a base salary of $250,000 per year. In addition, Mr. Kucinski is eligible to receive an annual bonus, which is targeted at 30% 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. Kucinski is also eligible to receive option grants at the discretion of our Compensation Committee. If we terminate Mr. Kucinski's employment without cause or Mr. Kucinski 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 his outstanding options will be accelerated by six months upon such termination. Mr. Kucinski is also subject to a customary non-disclosure agreement, pursuant to which Mr. Kucinski 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.

Outstanding Equity Awards at Fiscal Year-End Table – 2018

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, 2018.

	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	-	1,000,000	$ 0.98	Mar 21, 2028
	255,556	144,444	$ 3.32	Feb 20, 2027
	340,278	9,722	$ 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
Raphael Mannino	-	150,000	$ 0.44	Apr 29, 2028
	79,861	45,139	$ 3.32	Feb 20, 2027
	58,334	1,666	$ 0.43	Feb 4, 2026
	338,888	-	$ 0.95	Sep 1, 2025
	11,112	-	$ 0.48	Feb 27, 2025
Roelof Rongen (1)	333,333	-	$ 3.32	Mar 15, 2021
	333,333	-	$ 0.43	Mar 15, 2021
	300,000	-	$ 0.41	Mar 15, 2021
	350,000	-	$ 1.28	Mar 15, 2021
	350,000	-	$ 0.94	Mar 15, 2021
Gary Gaglione (2)	69,445	-	$ 3.32	Sep 30, 2020
	35,556	-	$ 0.43	Sep 30, 2020
	40,000	-	$ 0.41	Sep 30, 2020
	200,000	-	$ 0.94	Sep 30, 2020

(1)Mr. Rongen resigned on March 16, 2018.

(2)Mr. Gaglione retired on September 30, 2018.

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 10.6 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 15, 2019 the aggregate number of shares of common stock available for issuance in connection with awards granted under the 2013 Plan is 22,421,644 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 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 – 2018

The following table summarizes the annual compensation for our non-employee directors during 2018.

Name	Cash Compensation ($)	Stock Awards ($) (1)	Option Awards ($) (1)	Total ($)
Herbert Conrad	-	96,001	160,001	256,002
Eric Ende	35,750	35,751	160,001	235,002
Patrick G. LePore(2)	80,000	-	134,451	214,451
James S. Scibetta	-	75,002	160,001	235,003
Adam Stern	50,000	-	160,001	210,001
Matthew Wikler	-	61,627	353,704	415,331

(1) Amounts reflect the grant date fair value of stock awards and option awards granted in 2018 in accordance with Accounting Standards Codification Topic 718. These amounts do not correspond to the actual value that will be recognized by the directors.

(2) Mr. LePore was appointed as a member of the board of directors on September 5, 2018.

Compensation Committee Interlocks and Insider Participation

The Compensation Committee of the Board of Directors is currently composed of the following five non-employee directors: Eric Ende, Chair, Herbert J. Conrad, Patrick G. LePore, James Scibetta and Matthew Wikler. During the last fiscal year, the Compensation Committee was composed of the following four non-employee directors: Chair, Herbert J. Conrad, Eric Ende, James Scibetta and Matt 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. In addition, Messers. Conrad and Scibetta participated in the Company's warrant tender offer during fiscal 2017. See "Item 13. Certain Relationships and Related Party Transactions – Warrant Tender Offer" for additional information.

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 15, 2019 by:

- each of our stockholders who is known by us to beneficially own 5% or more of our common stock;
- each of our named executive officers and 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 113,465,670 shares outstanding as of March 15, 2019. 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 15, 2019 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		
Jennifer Lorenzo (1)	9,217,771	7.7%
Boxer Capital, LLC (2)	5,642,858	5.0%
Directors and Executive Officers		
Jerome D. Jabbour (3)	2,237,465	1.9%
Herbert Conrad (4)	5,287,414	4.6%
Eric Ende (5)	533,823	*%
Patrick LePore (6)	116,468	*%
James Scibetta (7)	1,218,719	1.1%
Adam Stern (8)	9,493,871	8.2%
Matthew Wikler (9)	409,604	*%
Raphael Mannino (10)	1,992,413	1.7%
Roelof Rongen (11)	5,206,082	4.5%
Gary Gaglione (12)	385,001	*%
Directors and Executive Officers as a group (10 persons) (13)	26,880,860	21.8%

* Less than 1%

(1) Based on information contained in a Schedule 13G filed on February 14, 2019. Includes 4,900,000 shares of common stock underlying shares of Series A Preferred Stock and 1,442,000 share of common stock underlying Series B Preferred Stock held by GJG Life Sciences, LLC. GJG Capital, LLC is the Managing Member of GJG Life Sciences, LLC, a limited liability company. Ms. Lorenzo is the Managing Member of GJG Capital, LLC and, as a result, Ms. Lorenzo and GJG Capital, LLC may be deemed to be indirect beneficial owners. The address for reporting persons is c/o GJG Capital, LLC. 107 Circle Road, Staten Island, NY 10304.

(2) Based on information contained in a Schedule 13G filed on February 14, 2019. The address for reporting persons is c/o GJG Capital, LLC. 107 Circle Road, Staten Island, NY 10304.

(3) Includes (i) 15 convertible preferred shares if converted to 30,000 common shares, and (ii) 1,827,778 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 15, 2019. Does not include 797,222 shares of common stock underlying options that are not exercisable within sixty days of March 15, 2019.

(4) Includes (i) 20,100 convertible preferred shares if converted to 400,000 common shares, and (ii) 854,511 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 15, 2019. Does not include 65,280 shares of common stock underlying options that are not exercisable within sixty days of March 15, 2019.

(5) Includes (i) 12 convertible preferred shares if converted to 24,000 common shares, and (ii) 440,531 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 15, 2019. Does not include 215,927 shares of common stock underlying options that are not exercisable within sixty days of March 15, 2019.

(6) Includes 116,468 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 15, 2019. Does not include 161,761 shares of common stock underlying options that are not exercisable within sixty days of March 15, 2019.

(7) Includes (i) 12 convertible preferred shares if converted to 24,000 common shares, and (ii) 656,641 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 15, 2019. Does not include 62,317 shares of common stock underlying options that are not exercisable within sixty days of March 15, 2019.

(8) Includes (i) 1,783,756 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 15, 2019, (ii) 656,641 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 15, 2019, (iii) 300,000 shares of common stock that are owned by Pavilion Capital Partners, LLC, which is wholly-owned by Mr. Stern, (iv) 300,000 shares of common stock that are owned by Piper Ventures Partners, LLC, which is wholly-owned by Mr. Stern, (v) 600,000 shares of common stock that are owned by SternAegis Ventures LLC, which is wholly-owned by Mr. Stern, (vi) 1,750,000 shares held by AKS Family Foundation and (vii) 2,939,483 shares of common stock held by AKS Family Partners (vii) 20,085 convertible preferred shares if converted to 370,000 common shares. Does not include 62,317 shares of common stock underlying options that are not exercisable within sixty days of March 15, 2019.

(9) Includes (i) 6 convertible preferred shares if converted to 12,000 common shares, and (ii) 300,948 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 15, 2019. Does not include 205,510 shares of common stock underlying options that are not exercisable within sixty days of March 15, 2019.

(10) Includes (i) 10 convertible preferred shares if converted to 20,000 common shares, and (ii) 547,848 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 15, 2019. Does not include 137,152 shares of common stock underlying options that are not exercisable within sixty days of March 15, 2019.

(11) Includes 1,666,666 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 15, 2019.

(12) Includes 345,001 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 15, 2019.

(13) See notes (3) through (12).

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, we describe below each transaction or series of similar transactions, since January 1, 2018, 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 and Matthew Wikler 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, 2018 and 2017, by EisnerAmper LLP, the Company's independent registered public accounting firm.

	Year Ended December 31,	
	2018	2017
	(in thousands)	
Audit Fees	$ 245	$ 182
Tax Fees	-	-
Total Fees	$ 245	$ 182

Audit Fees consist of fees for professional services and expenses relating to the audit of our annual financial statements and the review of our quarterly financial information.

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 Placement Agent Warrant (incorporated by reference to Exhibit 4.2 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
4.4	Registration Rights Agreement dated July 30, 2013 (incorporated by reference to Exhibit 4.3 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
4.5	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).
4.6	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).
4.7	Registration Rights Agreement dated March 31, 2015 between the Company and the investors named therein. (incorporated by reference to Exhibit 4.6 to the post-effective amendment No. 1 to Form S-1 filed with the SEC on April 17, 2015).
4.8	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).
10.1	Voting Agreement, dated July 30, 2013, by and among the Company and the stockholders named therein. (incorporated by reference to Exhibit 10.5 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).

10.2	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.) †
10.3	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). †
10.4	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	Employment Agreement, dated July 30, 2013, between the Company and Roelof Rongen (incorporated by reference to Exhibit 10.9 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014). †
10.6	Employment Agreement, dated July 30, 2013, between the Company and Abdel A. Fawzy. (incorporated by reference to Exhibit 10.11 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014). †
10.7	Employment Agreement effective as of October 4, 2013 between the Company and Jerome D. Jabbour (incorporated by reference to Exhibit 10.12 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014). †
10.8	Offer Letter, dated October 31, 2013, between the Company and Gary Gaglione (incorporated by reference to Exhibit 10.13 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014). †
10.9	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). †
10.10	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).
10.11	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). +
10.12	Employment Agreement, dated September 1, 2015, between Matinas Biopharma Holdings, Inc. and Raphael J. Mannino. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on September 1, 2015).
10.13	Employment Agreement, dated March 22, 2017, between Matinas Biopharma Holdings, Inc. and Roelof Rongen (incorporated herein by reference to Exhibit 10.23 to the Company's Annual Report on Form 10-K filed on March 31, 2017).†
10.14	Employment Agreement, dated March 22, 2017, between Matinas Biopharma Holdings, Inc. and Abdel Fawzy (incorporated herein by reference to Exhibit 10.24 to the Company's Annual Report on Form 10-K filed on March 31, 2017).†
10.15	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).

10.16	Controlled Equity OfferingSM Sales Agreement, dated April 28, 2017, by and between Matinas BioPharma Holdings, Inc. and Cantor Fitzgerald & Co. (incorporated herein by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on April 28, 2017).
10.17	Separation Agreement between Abdel Fawzy and Matinas BioPharma Holdings, Inc., dated January 29, 2018 (incorporated by reference to Exhibit 10.28 of the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed March 16, 2018 with the Securities and Exchange Commission). †*
10.18	Employment Agreement, effective as of April 18, 2017, by and between the Company and Dominick M. DiPaolo (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on April 18, 2017).†
10.19	Separation Agreement and General Release, between Roelof Rongen and Matinas BioPharma Holdings, Inc., dated March 16, 2018 (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on May 9, 2018)†*
10.20	Separation Agreement between Dominick DiPaolo and Matinas BioPharma Holdings, Inc., dated June 18, 2018. (incorporated herein by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2018)†*
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, 2018, formatted in XBRL (eXtensible Business Reporting Language), is filed electronically herewith: (i) Consolidated Balance Sheets as of December 31, 2018 and 2017; (ii) Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2018 and 2017; (iii) Consolidated Statement of Changes in Stockholders' Equity (Deficit) for the Years Ended December 31, 2018 and 2017; (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2018 and 2017; 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 April 1, 2019.

MATINAS BIOPHARMA HOLDINGS, INC.

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

By: */s/ Keith Kucinski*
Name: Keith 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)	April 1, 2019
/s/ Keith Kucinski Keith Kucinski	Chief Financial Officer (Principal Financial and Accounting Officer)	April 1, 2019
/s/ Herbert Conrad Herbert Conrad	Chairman of the Board	April 1, 2019
/s/ Patrick G. LePore Patrick G. Lepore	Vice Chairman of the Board	April 1, 2019
/s/ Eric Ende Eric Ende	Director	April 1, 2019
/s/ Matthew A. Wikler Matthew A. Wikler	Director	April 1, 2019
/s/ Adam K. Stern Adam K. Stern	Director	April 1, 2019
/s/ James S. Scibetta James S. Scibetta	Director	April 1, 2019

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 (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years then ended 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, 2018 and 2017, and the consolidated results of their operations and their cash flows for each of the years then ended, 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.

/s/ EisnerAmper LLP

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

EISNERAMPER LLP
Iselin, New Jersey
April 1, 2019

Matinas BioPharma Holdings Inc.
Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 12,446,838	$ 7,306,507
Restricted cash	100,000	155,431
Prepaid expenses	538,646	502,032
Total current assets	13,085,484	7,963,970
Non-current assets:		
Leasehold improvements and equipment - net	2,042,893	1,569,858
In-process research and development	3,017,377	3,017,377
Goodwill	1,336,488	1,336,488
Restricted cash - security deposits	461,000	535,999
Total non-current assets	6,857,758	6,459,722
Total assets	$ 19,943,242	$ 14,423,692
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 295,652	$ 582,867
Note payable	199,842	170,236
Accrued expenses	1,086,868	959,147
Stock dividends payable	1,174,286	-
Deferred revenue	-	29,937
Lease liability	83,245	26,975
Total current liabilities	2,839,893	1,769,162
Non-current liabilities:		
Deferred tax liability	341,265	848,185
Deferred rent liability	512,704	455,554
Lease liability - net of current portion	107,656	67,683
Stock dividends payable - long term	-	601,143
Total non-current liabilities	961,625	1,972,565
Total liabilities	3,801,518	3,741,727
Stockholders' equity:		
Series A Convertible preferred stock, stated value $5.00 per share, 1,600,000 shares authorized as of December 31, 2018 and 2017; 1,467,858 and 1,502,858 shares issued and outstanding as of December 31, 2018 and 2017, respectively, (liquidation preference - $8,513,576 at December 31, 2018)	5,583,686	5,716,825
Series B Convertible preferred stock, stated value $1,000 per share, 8,000 shares authorized and 4,819 shares outstanding as of December 31, 2018 (liquidation preference - $4,819,000 at December 31, 2018) No shares authorized or outstanding as of December 31, 2017.	4,196,547	-
Common stock par value $0.0001 per share, 250,000,000 and 250,000,000 shares authorized at December 31, 2018 and December 31, 2017, respectively; 113,287,670 issued and outstanding as of December 31, 2018; 93,371,129 issued and outstanding as of December 31, 2017	11,329	9,335
Additional paid in capital	72,294,921	56,230,347
Accumulated deficit	(65,944,759)	(51,274,542)
Total stockholders' equity	16,141,724	10,681,965
Total liabilities and stockholders' equity	$ 19,943,242	$ 14,423,692

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

Matinas BioPharma Holdings, Inc.
Consolidated Statements of Operations

	For the Year Ended December 31,	
	2018	2017
Revenue:		
Contract research revenue	$ 119,750	$ 149,687
Costs and Expenses:		
Research and development	6,787,474	9,010,499
General and administrative	7,978,821	7,641,592
Total costs and expenses	14,766,295	16,652,091
Loss from operations	(14,646,545)	(16,502,404)
Sale of New Jersey net operating loss	-	636,927
Other income, net	56,552	22,032
Benefit for income taxes	506,920	356,956
Net loss	$ (14,083,073)	$ (15,486,489)
Preferred stock series A & B accumulated dividends	(905,043)	(608,343)
Inducement charge from exercise of warrants	-	(16,741,356)
Net loss attributable to common shareholders	$ (14,988,116)	$ (32,836,188)
Net loss available for common shareholders per share - basic and diluted	$ (0.15)	$ (0.36)
Weighted average common shares outstanding:		
Basic and diluted	98,103,210	90,475,035

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

Matinas BioPharma Holdings, Inc.
Consolidated Statement of Stockholders' Equity
December 31, 2018

	Redeemable Convertible Preferred Stock A		Redeemable Convertible Preferred Stock B		Common Stock		Additional Paid – in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance, January 1, 2017	1,600,000	$ 6,086,350	-	$ -	58,159,495	$ 5,817	$ 36,237,503	$ (35,179,710)	$ 7,149,960
Stock-based compensation	-	-	-	-	-	-	2,453,352	-	2,453,352
Issuance of common stock as compensation for services	-	-	-	-	596,960	60	1,215,577	-	1,215,637
Issuance of common stock upon exercise of warrants, net warrant modification inducement charge	-	-	-	-	32,757,589	3,271	14,825,103	-	14,828,374
Issuance of common stock in exchange for preferred stock	(97,142)	(369,525)	-	-	971,420	97	369,428	-	-
Stock dividends paid	-	-	-	-	14,400	2	7,198	-	7,200
Issuance of common stock At-The-Market ("ATM"), net	-	-	-	-	871,265	88	1,122,186	-	1,122,274
Preferred dividends issued in common stock	-	-	-	-	-	-	-	(608,343)	(608,343)
Net loss	-	-	-	-	-	-	-	(15,486,489)	(15,486,489)
Balance, December 31, 2017	1,502,858	5,716,825	-	-	93,371,129	9,335	56,230,347	(51,274,542)	10,681,965
Stock-based compensation	-	-	-	-	-	-	3,217,309	-	3,217,309
Issuance of common stock as compensation for services	-	-	-	-	826,819	84	602,295	-	602,379
Issuance of Preferred Series B, net	-	-	8,000	6,966,668	-	-	-	-	6,966,668
Issuance of common stock in exchange for Preferred Series A	(35,000)	(133,139)	-	-	350,000	35	133,104	-	-
Issuance of common stock in exchange for Preferred Series B	-	-	(3,181)	(2,770,121)	6,362,000	636	2,769,485	-	-
Stock dividends issued in common stock	-	-	-	-	28,000	4	13,996	-	14,000
Issuance of common stock ATM, net	-	-	-	-	12,349,722	1,235	9,238,803	-	9,240,038
Issuance of warrants to placement agent	-	-	-	-	-	-	89,582	-	89,582
Preferred dividends accrued	-	-	-	-	-	-	-	(587,144)	(587,144)
Net loss								(14,083,073)	(14,083,073)
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

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

Matinas BioPharma Holdings Inc.
Consolidated Statements of Cash Flow

	For the Year Ended December 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (14,083,073)	$ (15,486,489)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	218,308	100,605
Deferred rent	57,150	157,349
Stock-based compensation expense	3,833,088	3,597,480
Deferred tax liability	(506,920)	(356,956)
Changes in operating assets and liabilities:		
Prepaid expenses	349,669	256,924
Other assets	-	4,845
Accounts payable	(287,215)	107,265
Accrued expenses and other liabilities	97,784	159,361
Net cash used in operating activities	(10,321,209)	(11,459,616)
Cash flows from investing activities:		
Purchases of leasehold improvements and equipment	(535,916)	(942,180)
Net cash used in investing activities	(535,916)	(942,180)
Cash flows from financing activities:		
Net proceeds from issuance of Series B convertible preferred stock and warrants	7,056,249	-
Net proceeds from exercise of warrants	-	14,828,373
Net proceeds from ATM sale	9,240,038	1,122,274
Payments of capital lease liability	(59,184)	(17,134)
Payments of note payable	(370,077)	(330,840)
Net cash provided by financing activities	15,867,026	15,602,673
Net increase in cash, cash equivalents and restricted cash	5,009,901	3,200,877
Cash, cash equivalents and restricted cash at beginning of period	7,997,937	4,797,060
Cash, cash equivalents and restricted cash at end of period	$ 13,007,838	$ 7,997,937
Supplemental non-cash financing and investing activities:		
Preferred stock conversion into common stock - series A	$ 133,139	$ 369,525
Preferred stock conversion into common stock - series B	$ 2,770,121	$ -
Warrant issued to placement agent	$ 89,582	$ -
Stock dividends accrual	$ 587,144	$ 608,343
Stock dividends issued	$ -	$ 7,200
Inducement charges for modification of warrants	$ -	$ 16,741,356
Stock dividends issued and converted to common stock	$ 14,000	$ -
Note payable for insurance premiums	$ 399,683	$ 383,030
Equipment acquired under capital lease	$ 155,427	$ 85,420
Leasehold improvements paid by landlord	$ -	$ 286,720
Unearned restricted stock grants	$ 58,100	$ 381,333

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, 2018, the Company had an accumulated deficit of approximately $65.9 million. The Company's net losses for the years ended December 31, 2018 and 2017 were approximately $14.1 million and $15.5 million, respectively.

The Company has been engaged in developing its lipid nano-crystal ("LNC") platform delivery technology and a pipeline of 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 FDA approval for one or more of its product candidates, which the Company does not expect to receive until 2023 at the earliest, 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 June 21, 2018, the Company completed a Series B Preferred Stock offering which raised $7.1 million after deducting issuance costs (see Footnote 9). In addition, during the year the Company utilized its Controlled Equity Offering^{SM} Sales Agreement ("Sales Agreement") with Cantor Fitzgerald & Co. to sell approximately 12.3 million shares of common stock, raising $9.2 million, net of fees. The Sales Agreement was entered into on January 13, 2017, and allows the Company, subject to certain restrictions and daily sales limits, to sell shares of common stock having an aggregate offering price of up to $30 million. As of December 31, 2018, the Company has sold approximately 13.2 million shares of common stock pursuant to the Sales Agreement generating gross proceeds of approximately $10.7 million.

As of December 31, 2018, the Company had cash and cash equivalents of approximately $12.4 million and restricted cash of $0.6 million. On March 19, 2019, the Company completed an underwritten public offering of common stock, generating gross cash proceeds of $30.5 million and net proceeds of approximately $28.2 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 (see Footnote 11). The Company believes the cash and cash equivalents on hand, along with net proceeds from the recently completed common stock offering, are sufficient to fund planned operations through April 2020.

Note 3 – Summary of Significant Accounting Policies

Basis of presentation and principles of consolidation

The accompanying consolidated financial statements include the consolidated accounts of Holdings and its wholly-owned operational subsidiaries, BioPharma, and Nanotechnologies. The accompanying consolidated financial statements have been prepared by the Company 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.

Use of estimates

The preparation of 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.

Certain accounting principles require subjective and complex judgments to be used in the preparation of financial statements. Accordingly, a different financial presentation could result depending on the judgments, estimates, or assumptions that are used. Such estimates and assumptions include, but are not specifically limited to, those required in the assessment of the impairment of intangible assets and the valuation of Level 3 fair value measurement of financial instruments and determination of stock-based compensation, contingent consideration and all acquired assets and liabilities.

Cash and cash equivalents

The Company considers all highly liquid instruments purchased with original maturity of three months or less to be cash equivalents to the extent the funds are not being held for investment purposes. Cash and cash equivalents include cash on hand, bank demand deposits and overnight sweep accounts used in the Company's cash management program.

Restricted Cash

The Company presents restricted cash with cash and cash equivalents in the Consolidated Statements of Cash Flows. 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, 2018 and 2017:

	As of December 31, (in thousands)	
	2018	2017
Cash and cash equivalents	$ 12,447	$ 7,307
Restricted cash included in current/long term assets	561	691
Cash, cash equivalents and restricted cash in the statement of cash flows	$ 13,008	$ 7,998

Concentration of credit risk

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash. Cash balances are maintained principally at two major U.S. financial institutions and are insured by the Federal Deposit Insurance Corporation ("FDIC") up to regulatory limits. At all times throughout the year ended December 31, 2018, the Company's cash balances exceeded the FDIC insurance limit. The Company has not experienced any losses in such accounts.

Leasehold improvements and equipment

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

Goodwill and other intangible assets

Goodwill is assessed for impairment at least annually on a reporting unit basis, or more frequently when events and circumstances occur indicating that the recorded goodwill may be impaired. In accordance with the authoritative accounting guidance 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 are required to perform further analysis to identify potential goodwill impairment and measure the amount of goodwill impairment loss to be recognized, if any. If we determine that it is more-likely-than-not that the fair value of the reporting unit is greater than its carrying amounts, further analysis is not required.

As defined in the authoritative guidance, 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, 2018 and 2017, the Company assessed goodwill impairment by performing a qualitative test for its reporting unit. During the qualitative reviews, 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 units is greater than their carrying amounts. There was no impairment of goodwill during the years ended December 31, 2018 and 2017.

The Company reviews other intangible assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. The authoritative accounting guidance allows a qualitative approach for testing indefinite-lived intangible assets for impairment, similar to the impairment testing guidance for goodwill. It allows the option to first assess qualitative factors (events and circumstances) that could have affected the significant inputs used in determining the fair value of the indefinite-lived intangible asset. The qualitative factors assist in determining whether it is more-likely-than-not that the indefinite-lived intangible asset is impaired. An organization may choose to bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to calculating its fair value. The Company's indefinite-lived intangible assets are IPR&D intangible assets. The Company used the qualitative test and concluded that it was more-likely-than-not that all indefinite-lived assets were not impaired and therefore, there were no impairments during the years ended December 31, 2018 and 2017, respectively.

Deferred rent

The Company records rent on a straight-line basis. Differences between monthly rent expenses and rent payments are recorded as deferred rent. Deferred rent is recorded in either an asset account (e.g., other current or noncurrent assets) when the cumulative difference between rent payments and rent expenses as of a balance sheet date is positive or a liability account (e.g., other current or noncurrent liabilities) when the cumulative difference is negative. Due to our escalating rents, the Company is currently recording a deferred rent liability. Deferred rent balances are classified as long-term liabilities in the accompanying consolidated balance sheets based upon the period when reversal of the liability is expected to occur.

Preferred stock dividends

Pursuant to the Certificate of Designations, the shares of Series A Preferred Stock earn dividends at a rate of 8.0% once per year on the first, second and third anniversary of the Initial Closing, which was July 29, 2016, payable to the holders of such Series A Preferred Stock in shares of common stock upon conversion. In addition, and subject to provisions detailed more fully in Footnote 9, the 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 the filing of the certificate of designation, which was June 19, 2008, for the Series B Preferred Stock with the Secretary of State of the State of Delaware, The dividends are payable to holders of such Series B Preferred Stock in shares of common stock upon conversion. 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.

Business combination

The Company accounts for acquisitions using the acquisition method of accounting which requires the recognition of tangible and identifiable intangible assets acquired and liabilities assumed at their estimated fair values as of the business combination date. The Company allocates any excess purchase price over the estimated fair value assigned to the net tangible and identifiable intangible assets acquired and liabilities assumed to goodwill. Transaction costs are expensed as incurred in general and administrative expenses. Results of operations and cash flows of acquired companies are included in the Company's operating results from the date of acquisition.

Beneficial conversion feature of convertible preferred stock

The Company accounts for the beneficial conversion feature on its convertible preferred stock in accordance with Accounting Standards Codification ("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. Beneficial conversion features 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 2018 and 2017 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, 2018.

Since the Company incurred net operating losses in every tax year since inception, the 2013 through 2017 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 generated in those years are utilized.

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 measurement of stock-based compensation is subject to periodic adjustments as the underlying equity instruments vest and is recognized as an expense over the period which services are received. 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 authoritative guidance requires forfeitures to be estimated at the time stock options are granted and warrants are issued and revised or adjustments made as they occur. 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.

Fair value measurements

ASC 820 “Fair Value Measurements” defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements. ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity’s own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under ASC 820 are described below:

- Level 1 - Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

- Level 2 - Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.

- Level 3 - Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management’s estimates of market participant assumptions.

In determining fair value, 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 cash and cash equivalents, current portion of restricted cash, accounts receivable, prepaid expenses, accounts payable, note payable, current portion of lease liability and accrued expenses approximate fair value due to the short-term nature of these instruments.

Basic and diluted net loss per common share

Basic and diluted net loss per share is computed by dividing net loss available to common shareholders by the weighted average number of shares outstanding during the period. 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 and warrants and conversion of preferred stock, would have an anti-dilutive effect. The following schedule details the number of shares issuable upon the exercise of stock options, warrants and conversion of preferred stock, which have been excluded from the diluted loss per share calculation as the inclusion would be anti-dilutive for the years ended December 31, 2018 and 2017:

	As of December 31, (in thousands)	
	2018	2017
Stock options	13,457	11,396
Preferred Stock and accrued dividend upon conversion	26,665	16,202
Warrants	5,799	5,958
Total	45,921	33,556

Revenue recognition

The Company applies ASC 606 to its current research grant. The Company currently has a research grant with its customer, the Cystic Fibrosis Foundation (“CFF”). There are no contract assets or liabilities associated with this grant. The contract has a single performance obligation which is the provision of research and development services related to the Company’s Cystic Fibrosis development program (the “Program”). The Company provides CFF with progress reports for each study it performs, summarizing the progress toward achieving the goals of the Program, and is required to submit a final progress report within 30 days after the completion of the Program. Subject to the submission and acceptance of milestone progress reports, the Company may be entitled to an additional payment of $0.1 million in the aggregate. As this contract is currently the Company’s only contract with a customer, disaggregation of revenue is not required.

Research and development, legal fees and other direct costs

Research and development costs are charged to operations as they are incurred. Legal fees and other direct costs incurred in obtaining and protecting patents are also expensed as incurred, due to the uncertainty with respect to future cash flows resulting from the patents and are included as part of general and administrative expenses in our consolidated statements of operations.

Recent accounting standards

In February 2016, the Financial Accounting Standards Board (the “FASB”) established 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.

The new standard is effective for the Company on January 1, 2019. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either: (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. If an entity chooses the second option, the transition requirements for existing leases also apply to leases entered into between the date of initial application and the effective date. The entity must also recast its comparative period financial statements and provide the disclosures required by the new standard for the comparative periods. The Company adopted Topic 842 on January 1, 2019 using the optional transition method to apply new guidance on January 1, 2019 rather than earliest periods presented and elected the 'package of practical expedients', which permits the Company not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. The Company will not elect the use-of-hindsight or the practical expedient pertaining to land easements; the latter not being applicable. The Company also elected the practical expedient to not separate lease and non-lease components for all leases.

The adoption of this standard will have a material effect on the Company's financial statements. While the Company continues to assess all of the effects of adoption, it currently believes the most significant effects relate to: (1) the recognition of new right-of-use assets and lease liabilities on the balance sheet for operating leases, and (2) providing significant new disclosures about leasing activities.

On the date of adoption, the Company will recognize additional operating liabilities, with corresponding right-of-use assets of the same amount based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases.

In August 2016, the FASB issued ASU No. 2016-15, "Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments", which amended the existing accounting standards for the statement of cash flows. The amendments provide guidance on eight classification issues related to the statement of cash flows. The amendments should be applied retrospectively to all periods presented. For issues that are impracticable to apply retrospectively, the amendments may be applied prospectively as of the earliest date practicable. The Company adopted the guidance in the first quarter of 2018. The adoption did not have a material impact on our consolidated financial statements.

In November 2016, the FASB issued ASU No. 2016-18 "Statement of Cash Flows (Topic 230): Restricted Cash" which requires that restricted cash and restricted cash equivalents be included as components of total cash and cash equivalents as presented on the statement of cash flows. This amendment is effective for periods beginning after December 15, 2017 for public entities. The Company adopted the guidance in the first quarter of 2018 on a retrospective basis.

In January 2017, the FASB issued ASU No. 2017-04 "Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment". The amendment simplifies the subsequent measurement of goodwill by eliminating Step 2 from the goodwill impairment test. Instead an entity should perform its goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. We are required to apply the amendments for the annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. We have evaluated this standard and believe it will not have a material impact on our consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09 "Compensation – Stock Compensation (Topic 718): Scope of Modification Accounting", which provides clarity and reduces both diversity in practice and cost and complexity when applying guidance in Topic 718. This amendment provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The amendments are effective for all entities for annual periods beginning after December 15, 2017. The Company adopted the guidance in the first quarter of 2018. The adoption did not have a material impact on our consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, "Compensation - Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting." These amendments expand the scope of Topic 718, Compensation - Stock Compensation (which currently only includes share-based payments to employees) to include share-based payments issued to nonemployees for goods or services. Consequently, the accounting for share-based payments to nonemployees and employees will be substantially aligned. The ASU supersedes Subtopic 505-50, Equity - Equity-Based Payments to Non-Employees. This standard is effective for public companies for annual periods beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted as long as ASU 2014-09 has been adopted. We are currently considering the impact of adoption but preliminarily believe that it will 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. We will be evaluating the impact this standard will have on our consolidated financial statements.

Reclassification

The company reclassified prior year deferred rent liability from current to long-term to conform with current year presentation.

Note 4 – Leasehold Improvements and Equipment

Leasehold improvements and equipment, summarized by major category, consist of the following for the years ended December 31, 2018 and 2017:

	Year Ended December 31, (in thousands)	
	2018	2017
Lab equipment	$ 1,054	$ 577
Furniture and fixtures	-	20
Equipment under capital lease	272	117
Leasehold improvements	1,156	1,097
Total	2,482	1,811
Less: accumulated depreciation and amortization	439	241
Leasehold improvements and equipment, net	$ 2,043	$ 1,570

Depreciation and amortization expense for the years ended December 31, 2018 and 2017 was approximately $218 thousand and $101 thousand, respectively.

The Company has entered into capital leases for lab equipment. During the years ended December 31, 2018 and 2017 the Company recognized interest expense of approximately $13 thousand and $6 thousand, respectively, associated with the lease payments.

Note 5 – Accrued Expenses

Accrued Expenses, summarized by major category, consist of the following for years ended December 31, 2018 and 2017:

	As of December 31, (in thousands)	
	2018	2017
Accrued payroll and incentives	$ 633	$ 721
Other accruals	454	238
Total	$ 1,087	$ 959

Note 6 – Commitments

Leases

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 thousand per month, increasing to approximately $14 thousand per month in the final year.

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 started on August 1, 2017, upon completion of construction. The monthly rent starts at approximately $43 thousand per month, increasing to approximately $64 thousand in the final year.

The Company records rent expense on a straight-line basis. Rent expense for the years ended December 31, 2018 and 2017 was approximately $745 thousand and $504 thousand, respectively.

Listed below is a summary of future minimum rental payments:

Year ending December 31,	Lease Commitments (in thousands)
2019	$ 713
2020	738
2021	663
2022	616
2023 and beyond	3,355
Total future minimum lease payments	$ 6,085

Research and development agreements

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

- On October 29, 2015, the Company agreed to provide funds in the amount of $132,405 per year under a CRADA to support NIH investigators to acquire technical, statistical and administrative support for research activities as well as to pay for supplies and travel expenses. The initial term of the CRADA was three years. The CRADA was amended and renewed on September 17, 2018, for an additional year without creating an additional funding commitment. On November 7, 2018, a second amendment was executed which created an additional funding commitment of $150,000, half of which was paid upon execution of the amendment. The balance is payable in May 2019.

- 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 encochleated drug products in patients with fungal, bacterial, or viral infections. The initial term of the CRADA was three years. The Company is in the final stages of amending and renewing the CRADA for an additional three years with an annual funding commitment of $200,000.

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 MAT2203 or MAT2501. Pursuant to the terms of the Series A Certificate of Designation for our outstanding Series A Preferred Stock, the Company may be required to pay royalties of up to $35 million per year. If and when the Company obtains FDA or EMA approval of MAT2203 and/or MAT2501, which the Company does not expect to occur before 2020, 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 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 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.

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 between Aquarius and Rutgers provides for, among other things, (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 $50,000 over the term of the license agreement.

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.

Note 7 – 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, 2018 and 2017, 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:

	Year Ended December 31, (in thousands)	
	2018	**2017**
Current expense (benefit):		
Federal	$ -	$ -
State	-	-
Foreign	-	-
Total current expense (benefit):	$ -	$ -
Deferred expense (benefit):		
Federal	$ (506,920)	$ (392,259)
State		35,303
Foreign	-	-
Total deferred expense (benefit):	$ (506,920)	$ (356,956)
Total income tax expense (benefit):	$ (506,920)	$ (356,956)

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,	
	2018	**2017**
Income at US Statutory Rate	21.00%	34.00%
State Taxes, net of Federal benefit	8.22%	8.50%
Permanent Differences	-0.48%	-4.55%
Tax Credits	0.68%	1.07%
Tax Law Change	3.47	-28.90%
Valuation Allowance	-30.41%	-7.87%
Discrete items	0.99%	-
	3.47%	2.25%

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 2018 and 2017 consist of the following:

	Year Ended December 31, (in thousands)	
	2018	**2017**
Share-based Compensation	$ 1,288	$ 498
Depreciation and Amortization	(11)	(1)
Accrued Liability	-	202
Net Operating Loss Carry-forwards	12,270	8,871
R&D Credit Carryforwards	1,314	849
Other	150	154
IPR&D	(848)	(848)
Total Deferred tax assets	$ 14,163	$ 9,726
Valuation allowance	(14,504)	(10,574)
Net deferred tax asset (liability)	$ (341)	$ (848)

On December 22, 2017, the Tax Cuts and Jobs Act ("The Act"), was signed into law by President Trump. The Act includes a number of provisions, including the lowering of the U.S. corporate tax rate from 35 percent to 21 percent, effective January 1, 2018 and the establishment of a territorial-style system for taxing foreign-source income of domestic multinational corporations. In December 2017, the SEC issued Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Act ("SAB118"), which allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment. The Company remeasured its deferred tax assets and liabilities as of December 31, 2017, applying the reduced corporate income tax rate and recorded a provisional decrease to the deferred tax assets of $4,935,000, with a corresponding adjustment to the valuation allowance. In the fourth quarter of 2018, we completed our analysis to determine the effect of the Tax Act and there were material adjustments as of December 31, 2018, including a reduction of the deferred tax liability due to the indefinite lived net operating loss generated in 2018.

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 carryback losses to previous years in which the Company had 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 $14.5 million and $10.6 million as of December 31, 2018 and 2017, respectively, representing an increase of $3.9 million.

As of December 31, 2018, the Company had Federal net operating loss carryforwards of $50.0 million. The Company also had federal and state research and development tax credit carryforwards of $1,384,000. Net operating losses generated prior to January 1, 2018, amounting to $38.0 million, will expire at various dates beginning in 2033, if not utilized. Net operating losses generated after January 1, 2018, amounting to $12.0 million, are limited to 80% utilization of current year income and no longer have an expiration.

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

Note 8 – Related Parties

Aegis Capital Corp. and Mr. Adam Stern

Mr. Adam Stern, a director of the Company, has been Head of Private Equity Banking at Aegis Capital Corp. and CEO of SternAegis Ventures since 2012. The Company has contracted with Aegis Capital in all of its finance raises from 2013 through 2018. Each of these transactions have been disclosed in our previous 10-K filings. A summary of these transactions are as follows:

- Aegis Capital Corp. acted as the Placement Agent for the Company's 2013 Private Placement which raised gross proceeds of $15 million. As the Placement Agent, Aegis Capital Corp. received an agent fee of $1.5 million and a non-accountable expense allowance of $450,000. In addition, the Placement Agent was issued 750,000 warrants at an exercise price of $2.00 per share and 1,500,000 warrants at an exercise price of $1.00 per share.

- Aegis Capital Corp. acted as the Placement Agent for the Company's 2015 Private Placement which raised gross proceeds of $10 million. The Placement Agent received a cash fee of $1 million and a non-accountable expense allowance of $300,000. The Placement agent was issued 2 million warrants to purchase shares at $ 0.50 per share and 2 million warrants to purchase shares at $0.75 a share.

- Aegis Capital Corp. acted as the Placement Agent for the Company's 2016 Series A Preferred Stock private placement which raised gross proceeds of $8 million. The Placement Agent was paid a cash fee of $800,000 and non-accountable expenses of $240,000. In addition, 1,600,000 warrants were issued to the Placement Agent at an exercise price of $0.50 per share.

- Aegis Capital Corp. was retained as our Warrant Agent for the Company's 2017 Offer to Amend and Exercise warrants, which raised gross proceeds of approximately $13.5 million. The Warrant Agent received a fee of 5% of the cash exercise prices paid by the holders of the warrants, excluding placement agent warrants. In addition, Aegis Capital Corp. was reimbursed for reasonable out-of-pocket legal fees and expenses, including a $35,000 non-accountable expense allowance.

- Aegis Capital Corp. acted as a selected dealer for our public offering of Series B Preferred Stock in June 2018, which raised gross proceeds of $8 million. In connection with the offering the Company agreed to issue placement agent warrants to purchase that number of shares of common stock equal to 1.5% of the aggregate number of shares of common stock underlying the shares of Series B Preferred Stock sold in the offering (not including any shares payable pursuant to the contemplated dividend thereunder). A total of 240,000 warrants were issued, of which Adam Stern and Aegis Capital Corp. were collectively issued 81,080.

Note 9 – Stockholders' Equity

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 the 2016 Private Placement, 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 the 2018 offering, 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 A Preferred Stock

As of December 31, 2018, the Company had 1,467,858 shares of Series A Preferred Stock outstanding.

Conversion:

Each share of Series A Preferred Stock is convertible at the option of the holder into such number of shares of the Company's common stock equal to the number of shares of Series A Preferred Stock to be converted, multiplied by the stated value of $5.00 (the "Stated Value"), divided by the Conversion Price in effect at the time of the conversion (the initial conversion price is $0.50, subject to adjustment in the event of stock splits, stock dividends, and a "fundamental transaction"). Based on the current conversion price and number of shares outstanding, the Series A Preferred Stock is convertible into 14,678,580 shares of common stock. A "fundamental transaction" means: (i) our merger or consolidation with or into another entity, (ii) any sale of all or substantially all of our assets in one transaction or a series of related transactions, or (iii) any reclassification of our Common Stock or any compulsory share exchange by which Common Stock is effectively converted into or exchanged for other securities, cash or property. Each share of Series A Preferred Stock will automatically convert into common stock upon the earlier of (i) notice by the Company to the holders that the Company has elected to convert all outstanding Series A Preferred Stock; provided however that in the event the Company elects to force automatic conversion pursuant to this clause (i), the conversion date for purposes of calculating the accrued Dividend (as defined below) is deemed to be the July 29, 2019, which is the third anniversary of the Initial Closing, (ii) three years from the Initial Closing, (iii) the approval of the Company's MAT2203 product candidate by the U.S. Food and Drug Administration or the European Medicines Agency (the "Regulatory Approval") or (iv) the Regulatory Approval of the Company's MAT2501 product candidate.

Beneficial Conversion Feature- Series A Preferred Stock (deemed dividend):

Each share of Series A Preferred Stock is convertible into shares of common stock, at any time at the option of the holder at a conversion price of $0.50 per share. On July 29, 2016, August 16, 2016, and September 12, 2016, the date of issuances of the Series A Preferred Stock, the publicly traded common stock prices were $0.67, $0.70, and $1.00 per share, respectively.

Based on the guidance in ASC 470-20-20, the Company determined that a beneficial conversion feature exists, as the effective conversion price for the Series A Preferred Stock at issuance was less than the fair value of the common stock into which the preferred shares are convertible. A beneficial conversion feature based on the intrinsic value of the date of issuances for the Series A Preferred Stock was approximately $4.4 million. During the year ended December 31, 2016, the beneficial conversion amount of approximately $4.4 million was then accreted back to the preferred shares as a deemed dividend and charged to accumulated deficit as the conversion rights were 100% effective at the time of issuance.

Liquidity Value and Dividends:

Pursuant to the Certificate of Designations, the Series A Preferred Stock accrue dividends at a rate of 8.0% once per year on the anniversary date of the Initial Closing, payable to the holders of such Series A Preferred Stock in shares of common stock upon conversion. Dividends of approximately $1.2 million have been accrued as paid-in-kind through December 31, 2018, with $.6 being accumulated in each of 2018 and 2017. During 2018, dividends of approximately $28 thousand were paid in shares of common stock upon conversions at the election of the holders. The holders of Series A Preferred Stock vote on an as converted basis with the Company's common stock holders. Upon any dissolution, liquidation or winding up, whether voluntary or involuntary, holders of Series A Preferred Stock are entitled to (i) first receive distributions out of Company assets in an amount per share equal to the Stated Value plus all accrued and unpaid dividends, whether capital or surplus before any distributions shall be made on any shares of common stock and (ii) second, on an as-converted basis alongside the common stock holders.

Royalty:

The Series A Preferred Stock includes the right, as a group, to receive: (i) 4.5% of the net sales of MAT2203 and MAT2501, in each case from and after the date, respectively, such candidate has received FDA or EMA approval, and (ii) 7.5% of the proceeds, if any, received by the Company in connection with the licensing or other disposition by the Company of MAT2203 and/or MAT2501 ("Royalty Payment Rights"). The royalty is payable so long as the Company has valid patents covering MAT2203 and MAT2501, as applicable. The Royalty Payment Rights are unsecured obligations of the Company. The royalty payment will be allocated to the holders based on their pro rata ownership of vested Series A Preferred Stock. The royalty rights that are part of the Series A Preferred Stock will vest, in equal thirds, upon each of the July 29, 2017, July 29, 2018, and July 29, 2019, which are the first, second and third anniversary dates of the Initial Closing, (each a "Vesting Date"); provided however, if the Series A Preferred Stock automatically converts into common stock prior to the 36 month anniversary of the initial closing, then the royalty rights that are part of the outstanding Series A Preferred Stock shall be deemed to be fully vested as of the date of conversion. Even if the Series A Preferred Stock is purchased after the initial closing, the vesting periods for the royalty rights that are part of the Series A Preferred Stock shall still be based on the Vesting Dates. During the first 36 months following the initial closing, the right to receive a royalty will follow the Series A Preferred Stock; after July 29, 2019 the royalty payment rights may be transferred separately from the Series A Preferred Stock subject to available exemption from registration under applicable securities laws. The Company believes that such rights are not separable free-standing instruments requiring bifurcation at the date of transaction. The Company may recognize a deemed dividend for the estimated fair value of the vested portion of the royalty rights in future periods. As of December 31, 2018 and 2017, no accrual has been recorded for royalty payments as it is not probable at this time that any amount will be paid.

Classification:

The shares of Series A Preferred Stock are classified within permanent equity on the Company's consolidated balance sheet as they do not meet the criteria that would require presentation outside of permanent equity under ASC 480 *Distinguishing Liabilities from Equity*.

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, 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. 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, 2018, there were 4,819 shares of Series B Preferred Stock outstanding.

Conversion:

Optional Conversion. Subject to the Beneficial Ownership Limitation, each share of Series B Preferred Stock will be convertible into shares of 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 9,638,000 shares of common stock. Dividends will not accrue and will not be paid following optional conversion.

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 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 the 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. Both the Optional and Automatic conversion features were evaluated to determine if either represents a BCF. Based on the guidance in ASC 470-20-30, the Company determined that a BCF does not exist, 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.

Beneficial Ownership Limitation. The Company may not effect 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 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 will be entitled to receive dividends payable only to the holders of Series B Preferred Stock in common stock upon conversion 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. Dividends of approximately $.3 were accumulated in 2018.

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 the Series B 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.

Classification:

The shares of Series B Preferred Stock are classified within permanent equity on the Company's condensed consolidated balance sheet as they do not meet the criteria that would require presentation outside of permanent equity under ASC 480 *Distinguishing Liabilities from Equity*.

Warrants

2017 Warrant Tender Offer:

On January 13, 2017, the Company completed its tender offer to amend and exercise certain categories of existing warrants.

Pursuant to the Offer to Amend and Exercise, an aggregate of 30,966,350 warrants were tendered by their holders and were amended and exercised in connection therewith for an aggregate exercise price of approximately $15.5 million, including the following: 3,750,000 Formation Warrants; 754,000 Merger Warrants; 7,243,750 2013 Investor Warrants; 500,000 Private Placement Warrants; 14,750,831 2015 Investor Warrants; 722,925 $2.00 Placement Agent (PA) Warrants (of which 721,987 were exercised on a cashless basis); 1,426,687 $1.00 PA Warrants (of which 1,424,812 were exercised on a cashless basis); and 1,818,157 $0.75 PA Warrants (of which 1,774,017 were exercised on a cashless basis). The gross cash proceeds from such exercises were approximately $13.5 million and the net cash proceeds after deducting warrant solicitation agent fees and other estimated offering expenses were approximately $12.7 million. Prior to the Offer to Amend and Exercise, the Company had 58,159,495 shares of common stock outstanding and warrants to purchase an aggregate of 40,255,234 shares of common stock. Immediately following the Offer to Amend and Exercise (after the effect of certain cash and cashless exercises), the Company issued in exchange for the warrants 29,666,782 common shares.

The Company considers the warrant amendment to be of an equity nature as the amendment allowed the warrant holder to exercise a warrant and receive a common share which represents an equity for equity exchange. Therefore, the change in the fair value before and after the modification of approximately $16.7 million will be treated as a change in additional paid in capital (APIC) as an inducement charge. The cash received upon exercise in excess of par is also accounted for through APIC.

The Company retained Aegis Capital Corp. (“Aegis Capital”) to act as its Warrant Agent for the Offer to Amend and Exercise pursuant to a Warrant Agent Agreement. Aegis Capital received a fee equal to 5% of the cash exercise prices paid by holders of the warrants (excluding the placement agent warrants) who participated in the Offer to Amend and Exercise. In addition, the Company agreed to reimburse Aegis Capital for its reasonable out-of-pocket expenses and attorney’s fees, including a $35,000 non- accountable expense allowance.

Warrants outstanding:

As of December 31, 2018, the Company had outstanding warrants to purchase an aggregate of 5,799,429 shares of common stock at exercise prices ranging from $0.50 to $0.75 per share.

The 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 of the warrants. No fractional shares will be issued upon the exercise of the warrants. The exercise price and the number of warrant shares purchasable upon the exercise of the Investor Warrants (as opposed to Placement Agent Warrants) are subject to adjustment upon the occurrence of certain events, which include stock dividends, stock splits, combinations and reclassifications of the Company capital stock or similar “organic changes” to the equity structure of the Company (see Warrant table below). Accordingly, pursuant to ASC 815, the warrants are classified as equity.

The Company may call the warrants, other than the Placement Agent Warrants, at any time the common stock trades above $ 3.00 (for 20 million warrants issued in 2015) 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 Placement Agent Warrants do not have a redemption feature. The Placement Agent Warrants may be exercised on a “cashless” basis. Such term is a contingent feature and within the control of the Company, therefore does not require liability classification

A summary of warrants outstanding as of December 31, 2018 is presented below, all of which are fully vested:

	Shares (in thousands)
Outstanding at January 1, 2017	40,255
Issued	-
Exercised	(3,331)
Tendered	(30,966)
Expired	-
Outstanding at December 31, 2017	5,958**
Issued	240
Exercised	-
Tendered	-
Expired	(399)
Outstanding at December 31, 2018	5,799*

* Weighted average exercise price for outstanding warrants is $0.61.
** Weighted average exercise price for outstanding warrants is $0.70.

Note 10 – Stock-based Compensation

In August 2013, the Company adopted the 2013 Equity Compensation Plan (the "Plan"), which 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 shares on the date of grant as determined by the Board Committee. The Board 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 years. The term of the options is no longer than ten years. As of December 31, 2018, the Company had 17,890,137 shares of common stock authorized for issuance under the plan.

With the approval of the Board of Directors and majority 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:

	Year Ended December 31, (in thousands)	
	2018	2017
Research and Development	$ 896	$ 1,016
General and Administrative	2,937	2,581
Total	$ 3,833	$ 3,597

The following table contains information about the Company's stock plan at December 31, 2018:

	Awards Reserved for Issuance	Awards Issued	Awards Available for Grant
2013 Equity Compensation Plan (in thousands)	17,890	15,515*	2,375

* 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, 2017 to December 31, 2018 (options in thousands):

	Number of Options	Weighted Average Exercise Price	Weighted Average Contractual Term in Years
Outstanding at January 1, 2017	8,290	$ 0.85	7.3
Granted	3,568	$ 2.77	
Exercised	-	-	
Forfeited	(436)	$ 2.37	
Cancelled	(26)	0.63	
Expired	-	-	
Outstanding at December 31, 2017	11,396	$ 1.40	7.8
Granted	4,300	$ 0.76	
Exercised	-		
Forfeited	(1,262)	$ 2.08	
Cancelled	-		
Expired	(977)	$ 1.32	
Outstanding at December 31, 2018	13,457	$ 1.13	6.2

The following table summarizes outstanding options at December 31, 2018, by their exercise price:

Range of Exercise Prices	Number Outstanding (in thousands)	Weighted Average Exercise Price Per Share
$0.41 - $0.63	2,835	$ 0.43
$0.68 - $1.12	6,521	0.88
$1.24 - $1.95	2,585	1.31
$2.74 - $3.32	1,516	3.23
	13,457	$ 1.13

As of December 31, 2018, the number of vested shares underlying outstanding options was 9,514,815 at a weighted average exercise price of $1.17. The aggregate intrinsic value of in-the-money options outstanding as of December 31, 2018 was $0.5 million. The aggregate intrinsic value is calculated as the difference between the Company's closing stock price of $0.60 on December 31, 2018, and the exercise price of options, multiplied by the number of options. As of December 31, 2018, there was approximately $3.0 million of total unrecognized share-based compensation. Such costs are expected to be recognized over a weighted average period of approximately 2.2 years.

All options expire ten years from date of grant. Options granted to employees prior to 2018 vest entirely and evenly over three years. The Company changed its standard vesting terms at the end of 2017 and recent option grants 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 ending December 31, 2017 and December 31, 2018, the Company granted restricted stock awards for 826,819 and 596,960 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 pursuant to a consulting agreement. The Company values restricted stock awards at the fair market value on the date of grant. The Company recorded as general and administrative expense $616 thousand and $1,144 thousand in the consolidated statement of operations for the year ended December 31, 2018 and 2017, respectively.

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 consulting agreement, whereby the award vesting period and the service period defined pursuant to the terms of the consulting agreement may be different. Stock options issued to consultants are revalued quarterly until fully vested, with any change in fair value expensed. The following weighted-average assumptions were used to calculate share-based compensation:

	For the Year Ended December 31,	
	2018	2017
Volatility	105.85% - 111.31%	67.8% - 109.63%
Risk-free interest rate	2.29% - 3.08%	1.89% - 2.37%
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 expected term of share option grants.

The expected stock price volatility assumption is based the Company's historical stock price volatility.

Note 11 – Subsequent Events

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 $30.5 million. Net proceeds after deducting underwriting discounts and commissions and other estimated offering expenses are expected to be approximately $28.2 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. If the underwriters exercise the option in full, additional net proceeds of approximately $4.2 million will be generated. 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 ofapproximately $2.3 million.

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-8 (Nos. 333-198488, 333-203141, 333-210495, 333-215456 and 333-222912) and Form S-3 (No. 333-217106) of our report dated April 1, 2019, on our audit of the consolidated financial statements as of December 31, 2018 and 2017 and for each of the years then ended, which report is included in this Annual Report on Form 10-K.

EISNERAMPER LLP
Iselin, New Jersey
April 1, 2019

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, 2018 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: April 1, 2019

/s/ Jerome D. Jabbour
Jerome D. Jabbour
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Keith Kucinski, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2018 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: April 1, 2019

/s/ Keith Kucinski
Keith 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, 2018 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 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: April 1, 2019

/s/ Jerome D. Jabbour
Jerome D. Jabbour
Chief Executive Officer
(Principal Executive Officer)

Date: April 1, 2019

/s/ Keith Kucinski
Keith 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.