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

FORM 10-K

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

For the fiscal year ended December 31, 2015

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: 333-193455

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

Securities registered pursuant to Section 12(g) of the Act:
None.

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

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

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

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

Indicate by check mark 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☒

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

The aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates of the registrant computed by reference to the price at which the common stock was last sold on June 30, 2015 was approximately $34.5 million.

As of March 1, 2016 there were 57,180,148 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, 2015

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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 limited operating history;
- 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, which are still in an early development stage;
- our reliance on proprietary cochleate drug delivery technology, which is licensed to us by Rutgers University;
- our ability to manufacture GMP batches of our product candidates which are required for pre-clinical and clinical trials and, subsequently, if regulatory approval is obtained for any of our products, our ability to manufacture commercial quantities;
- our ability to complete required clinical trials for our lead product candidate and other product candidates and obtain approval from the FDA or other regulatory agents in different jurisdictions;
- our dependence on third-parties, including third-parties to manufacture and third-party CROs (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;

- acceptance of our business model by investors;
- the accuracy of our estimates regarding expenses and capital requirements;
- our ability to adequately support growth; and
- the factors listed under the headings “Risk Factors” elsewhere in this report and other reports that we file with the Securities and Exchange Commission.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and we believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

Item 1. Business

Company Overview

We are a clinical-stage biopharmaceutical company focused on identifying and developing safe and effective broad spectrum therapeutics for the treatment of serious and life-threatening infections. We are developing a pipeline of product and development candidates, with an initial focus on serious fungal and bacterial infections. On January 29, 2015, we completed the acquisition of Aquarius Biotechnologies Inc., (referred to as the "Aquarius Merger" throughout this document), a New Jersey-based, early-stage pharmaceutical company focused on the development of differentiated and orally delivered therapeutics based on a proprietary, lipid crystal drug delivery platform called "cochleate delivery technology".

Our proprietary cochleate delivery technology platform, licensed from Rutgers University on an exclusive worldwide basis, is designed specifically for the targeted and safe delivery of pharmaceuticals directly to the site of infection or inflammation. This innovative technology utilizes lipid-crystal nano-particle cochleates to nano-encapsulate existing drugs, which is designed to make them safer, more tolerable, less toxic and orally bioavailable. We believe this platform represents a significant innovation that may result in meaningful improvements to currently available therapies to treat numerous life-threatening diseases, including serious fungal infections and multi-drug resistant, or MDR, gram-negative bacterial infections.

Currently, we are focused on the anti-infectives market and on drug candidates which we believe demonstrate the value and innovation associated with our unique delivery platform technology. We believe initially focusing on the anti-infectives market has distinct advantages for the development of products which meet significant unmet medical need, including:

- a current regulatory environment which provides small development and clinical stage companies incentives and opportunities to reduce development cost and timeline to market for anti-infective drug candidates;
- traditional high correlation between efficacy and safety data in preclinical animal models and the outcome of human clinical trials with these product candidates;
- attractive commercial opportunities for a product differentiated in its safety profile, mode of action and oral bioavailability positioned against current therapies with significant side effects, limited efficacy and intravenous delivery resulting in lack of convenience, compliance and at a significant burden to the cost of healthcare; and
- an ability to commercialize anti-infective products with a focused and cost-efficient sales and marketing organization

We currently have two clinical-stage products designed for the treatment of infectious disease. Our lead product candidate is MAT 2203, a novel oral formulation of a broad spectrum anti-fungal drug called amphotericin B which uses our cochleate delivery technology. We are initially developing MAT2203 for the treatment of Candida infections. A Phase 1a study has been completed and demonstrated that MAT2203 was generally well tolerated at all dosage levels with no serious adverse events reports and no laboratory or renal function abnormalities observed. We are currently screening and enrolling patient in a Phase 2a study of MAT2203 in collaboration with the National Institute of Allergy and Infectious Diseases, or NIAID, of the National Institutes of Health, or NIH, and, assuming the NIH meets the anticipated clinical timelines, we anticipate announcing results of this study during 2016. The U.S. Food and Drug Administration, or FDA, has granted MAT2203 designations for Qualified Infectious Disease Product, or QIDP, and Fast Track for the treatment of invasive candidiasis and invasive aspergillosis. 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 the FDA to expedite drug development and review. Neither Fast Track designation nor QIDP designation change the standards for approval and we can provide no assurances that we can maintain QIDP or Fast Track designations for MAT2203 or that such designations will result in faster regulatory review. MAT2203 has also received designation from FDA as an Orphan Drug for the treatment of leishmaniasis and we expect to file for additional Orphan Drug designations for MAT2203. The orphan drug designation provides eligibility for seven years of market exclusivity in the United States upon FDA approval, a waiver from payment of user fees, an exemption from performing clinical studies in pediatric patients and tax credits for the cost of clinical research, if we maintain orphan drug designation. The seven-year period of marketing exclusivity provided through orphan designation combined with an additional 5 years of marketing exclusivity by the QIDP designations would position MAT2203 for eligibility of a total of 12 years of marketing exclusivity to potentially be granted at the time of FDA approval.

Our second clinical stage product candidate is MAT2501, an orally administered, encochleated formulation of the broad spectrum aminoglycoside antibiotic amikacin which may be used to treat different types of multidrug-resistant bacteria, including non-tubercular mycobacterial infections (NTM), as well as various multidrug-resistant gram negative and intracellular bacterial infections. Currently, amikacin cannot be absorbed enterally and must be given by intravenous, intramuscular or nebulization routes with the significant risk of nephrotoxicity and ototoxicity, which makes it an impractical choice when treating serious infections which often require long courses of therapy, often 12 to 18 months or longer. MAT2501, taking advantage of its innovative, nano-encapsulation delivery technology, is being developed to be orally administered, and is designed to be a safer and targeted therapy for improved treatment of these serious and life-threatening bacterial infections in patients, including those who are severely immunocompromised. We are initially developing MAT2501 for the treatment of NTM. NTM causes many serious and life-threatening diseases, including pulmonary disease, skin and soft tissue disease, joint infections and, in immunocompromised individuals, disseminated infection. The most common clinical manifestation of NTM disease is pulmonary, or lung, disease. NTM lung infection occurs when a person inhales the organism from their environment. There are about 50,000 to 90,000 people with NTM pulmonary disease in the United States, with a much higher prevalence in older adults, and these numbers appear to be increasing. However, NTM can affect any age group. Without treatment, the progressive lung infection caused by NTM results in severe cough, fatigue, and often weight loss. In some people NTM infections can become chronic and require ongoing treatment. Treatment may be difficult because NTM bacteria may be resistant to many common types of antibiotics. Severe NTM lung disease can have a significant impact on quality of life and can be life-threatening. We are also exploring the development of MAT2501 for the treatment of a variety of serious and acute bacterial infections, including the treatment of gram negative bacterial infections, currently the most significant unmet medical need identified by infectious disease specialists. We recently filed an Investigational New Drug (IND) application with FDA and were clear to commence Phase 1 clinical studies in January 2016. We plan to initiate the first Phase 1 study of MAT2501 during 2016. The U.S. FDA has already granted MAT2501 designations for Orphan Drug and QIDP for the treatment of non-tuberculous mycobacteria. If we maintain orphan drug and QIDP designations, the seven-year period of marketing exclusivity provided through orphan designation combined with an additional 5 years of marketing exclusivity by the QIDP designations positions MAT2501 to be eligible for total of 12 years of marketing exclusivity which may be granted at the time of FDA approval.

We are currently exploring strategic partnering options for our legacy cardiovascular drug, MAT9001, which has been developed and targeted to date for the treatment of very high triglycerides and MAT8800, our discovery program seeking to identify product candidates derived from omega-3 fatty acids for the treatment of non-alcoholic fatty liver disease.

Strategy

Our goal is to become a fully integrated biopharmaceutical company that discovers, develops and commercializes novel anti-infective medicines using our proprietary delivery platform technology. Key elements of our strategy include:

- Focus on the continued development of our current clinical stage anti-infective product candidates, including commencing and completing the planned Phase2a clinical trial with MAT2203 conducted in cooperation with and funded by the NIH and advancing MAT2501 into Phase 1 clinical studies during 2016. We intend to target those indications which, if approved, would result in being able to take advantage of the 12 years of product exclusivity afforded through FDA designation as a QIDP and Orphan drug product;

- Build a significant portfolio of pharmaceutical products using our proprietary cochleate delivery technology platform in conjunction with pharmacologically active compounds that currently have both regulatory approval and broad market adoption, and thereby, we believe, potentially reducing development risk, regulatory approval process time and market adoption risk for our products;

- Identify strategic collaborations with one or more pharmaceutical partners through which we can utilize our unique and proprietary platform delivery technology to improve the clinical profile of one or more active pharmaceutical ingredients either in development or currently marketed.

- Identify one or more strategic or financial partners to continue the development of our legacy cardiovascular MAT9001 product; and

- Develop or find existing manufacturing space in order to grow our capabilities to manufacture product in a compliant, cGMP facility in order to supply products for clinical development and, ultimately, commercial production in an effort to retain exclusive knowledge of the process and intellectual property associated with our platform delivery technology;

Our Anti-Infective Product Candidates

MAT2203

Product Profile

MAT2203 is an orally-administered, encochleated 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 available but its IV-delivery results in significant treatment-limiting side effects, including nephrotoxicity. The ability to provide amphotericin B orally using our proprietary and novel oral formulation may offer a new and promising alternative for patients and doctors. In a clinical Phase 1a single-dose, double-blind, dose-escalating, pharmacokinetic study of 48 healthy volunteers, oral MAT2203 demonstrated a positive safety and tolerability profile with no serious adverse events reported, including little or no nephrotoxicity as compared to placebo.

Antifungal Market

According to a February 2012 article in Genetic Engineering & Biotechnology News, the world market for systemic antifungal therapies was estimated to be in excess of $6 billion in 2011 and was expected to grow by as much as 4% a year. This market for serious fungal infections is currently served by only three major drug classes: triazoles, polyenes and echinocandins. Of these, the azole class is currently dominant with voriconazole as the market leading agent. The echinocandins are the latest class of agent to be introduced to the market but mortality remains high. Increasing resistance is being seen amongst Candida and Aspergillus species, particularly to azoles. The market for systemic antifungals is driven by annual increases in the susceptible immune compromised patient population.

Azole antifungals are available in oral formulations and are typically well tolerated, but resistance has developed, and toxicities that occur with prolonged use include hepatotoxicity, fluoride toxicity, and photosensitivity (with voriconazole). Echinocandins (eg, caspofungin and micafungin) are very well tolerated but are only available as IV formulations and resistance has developed. Polyene derivatives, such as amphotericin B, are sometimes administered for topical treatment of oral and esophageal candida infections as an oral suspension though it is not widely available, is not very effective, and may irritate the oral and esophageal tissues.

Our lead anti-infective product candidate, MAT2203, is an application of our cochleate 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, aspergillosis and leishmaniasis. To date, there have been 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 significant side effects (including nephrotoxicity, or a poisonous effect on the kidneys). Encapsulating the amphotericin B drug with our cochleate delivery technology provides a potential opportunity for the drug to be taken orally with targeted delivery to infected cells, which we believe may have fewer side effects than the currently available IV-formulations of amphotericin B.

Development History of MAT2203

MAT2203 was extensively studied in animal model studies of various fungal infections including invasive candidiasis, aspergillosis, and visceral leichmaniasis.

The data from animal studies for MAT 2203, our cochleate lipid-crystal nano-particle formulation of amphotericin B, indicate a significant side-effect advantage over amphotericin B formulations, which we believe is based on two phenomena:

- The lipid-crystal nano-particle is a solid particle, and does not significantly “leak” its drug content while circulating. The particle releases its medication pay-load only when inside the target cells, and thus protects the kidney and other sensitive tissues from many of the amphotericin B side effects.
- Because of this targeted approach, the required dose level is typically lower than other formulations. The lower dose further contributes to a more beneficial side-effect profile.

In addition, in the vast majority of these animal studies the MAT2203 product was administered orally; in the remainder of these animal studies the MAT2203 product was administered via IV. If confirmed in our ongoing Phase 2a human efficacy study, the oral formulation is a second major differentiator of our technology which offers significant health-economic benefit since patients do not need to stay in the hospital to receive the therapy. Because of these strong differentiators brought by the cochleate lipid-crystal nano-particle technology, we believe that MAT2203, if eventually approved by the FDA, may be able to obtain a significant market share of the fungal infection treatment market.

An IND application for MAT2203 was filed with the Food and Drug Administration, or FDA, in late 2006. In a clinical Phase 1a single-dose, double-blind, dose-escalating, pharmacokinetic (PK) study of 48 healthy volunteers MAT 2203 demonstrated a positive safety and tolerability profile with no serious adverse events reported.

Development Plan for MAT2203 – Phase 2a

The NIH is currently enrolling, screening and preparing to dose patients in a Phase 2a study of encochleated amphotericin B (CAMB) in patients with mucocutaneous (esophageal, oropharyngeal, vulvovaginal) candidiasis who are refractory or intolerant to standard non-intravenous therapies. This is an open-label, dose-titration trial in up to 16 patients to study the efficacy, safety, and pharmacokinetics of oral CAMB in the treatment of mucocutaneous candidiasis. Initially, CAMB will be administered at 200 mg/day (100 mg twice daily, or BID) for 2-weeks. If a patient experiences a clinical response after 2 weeks, then treatment will be extended for 2 more weeks. If there is no clinical response but study drug is tolerated, then dosage will be escalated to 400 mg/day (200 mg BID). If after escalation there is a clinical response after 2 weeks, then treatment will be extended for 2 more weeks. If there is no clinical response and study drug is tolerated, then dosage can be escalated again to 800 mg/day (400 mg BID) for an additional 2 weeks. The primary objective of the trial is to assess the clinical response to treatment of mucocutaneous candidiasis infections in patients who are refractory or intolerant to standard non-intravenous therapies after treatment for 14-days with the highest titrated dosage of CAMB per patient. Secondary objectives include pharmacokinetics, mycological response, and safety. Assuming that the NIH meets the proposed timeline for this study, we expect to release data later in 2016 following evaluation and discussion with the NIH.

MAT2501 – Targeting Chronic and Acute Bacterial Infections

Product Profile

MAT2501, an orally-administered, encochleated formulation of the broad spectrum IV-only aminoglycoside antibiotic agent amikacin, utilizes the Company's proprietary, lipid-crystal, nanoparticle delivery technology. Amikacin is currently used to treat different types of chronic and acute bacterial infections, including NTM infections and various multidrug-resistant gram negative bacterial infections. IV-administered amikacin is associated with major side effects including nephrotoxicity and ototoxicity (permanent loss of hearing). MAT2501 is specifically designed to provide targeted delivery of the potent antibiotic amikacin while providing a significantly improved safety and tolerability profile. In preclinical studies MAT2501 demonstrated oral bioavailability and targeted delivery of amikacin directly to the site of infection in both pulmonary (lung) and disseminated NTM infections. We recently received FDA clearance to initiate a Phase 1 clinical study of MAT2501 for the treatment of NTM infections. The FDA has also designated MAT2501 as a QIDP and an Orphan Drug for the treatment of NTM infections. We intend to initially develop MAT2501 for the treatment of NTM infections and will also explore the development of MAT2501 for the treatment of a variety of multi-drug resistant, gram negative bacterial infections. If approved, we believe MAT2501 would become the first orally bioavailable aminoglycoside and represent a significant improvement over existing therapies from a treatment and health economic perspective.

NTM Market Opportunity

Nontuberculous mycobacteria (NTM) are naturally occurring organisms found in water, soil, plants and animals. NTM causes many serious and life-threatening diseases, including pulmonary disease, skin and soft tissue disease, joint infections and, in immunocompromised individuals, disseminated infection. The most common clinical manifestation of NTM disease is pulmonary, or lung, disease. NTM lung infection occurs when a person inhales the organism from their environment. While most people do not become ill, some individuals develop a slow, progressive and destructive disease when NTM infects the airways and lung tissue leading to inflammation in the respiratory system. Individuals susceptible to the infection often have an unknown defect in their lung structure or immune system, lung damage from a pre-existing chronic obstructive pulmonary disease (COPD), such as emphysema and bronchiectasis, cystic fibrosis, or an immune deficiency disorder, such as HIV or AIDS.

There are about 50,000 to 90,000 people with NTM pulmonary disease in the United States, with a much higher prevalence in older adults, and these numbers appear to be increasing. However, NTM can affect any age group. Without treatment, the progressive lung infection caused by NTM results in severe cough, fatigue and weight loss and may ultimately lead to death. In some people NTM infections can become chronic and require ongoing and long term treatment. Treatment may be difficult because NTM bacteria may be resistant to many common types of antibiotics. Severe NTM lung disease can have a significant impact on quality of life and can be life-threatening. There are no products specifically indicated for the treatment of NTM disease in the U.S., Europe or Canada. Current guideline-based approaches involve multi-drug regimens that may cause severe side effects and treatments can be as long as two years or more.

Drug-Resistant Antibiotic Market

Physicians commonly prescribe antibiotics to treat patients with infectious diseases that are either known, or presumed, to be caused by bacteria. According to IMS Health, in 2011 approximately $41 billion was spent on antibiotic drugs worldwide, of which almost $9 billion was spent in the United States. The widespread use of antibiotics has resulted in a rapid increase in bacterial infections that are resistant to multiple antibacterial agents.

Bacterial infections are caused by a variety of different types of bacteria and the infections they cause can range from mild to serious, life-threatening infections requiring immediate treatment. Bacteria are broadly categorized as Gram-positive, Gram-negative, atypical or anaerobic. Gram-positive bacteria possess a single membrane and a thick cell wall and turn dark-blue or violet when subjected to a laboratory staining method known as Gram's method. Common causes of Gram-positive bacterial infections include species of *Staphylococcus* , such as methicillin-resistant *Staphylococcus aureus* , or MRSA, *Streptococcus* and *Enterococcus* . Gram-negative bacteria have two membranes with a thin cell wall and, when subjected to Gram's method of staining, lose the stain or are decolorized. According to The New England Journal of Medicine, the most common cause of Gram-negative infection is *Escherichia coli* , or *E. coli* . Less prevalent Gram-negative bacteria strains include species of *Acinetobacter* , *Klebsiella, Salmonella* and *Pseudomonas* . Atypical bacteria, such as *Mycoplasma* species, have modified cell walls and are neither Gram-positive nor Gram-negative. Anaerobic bacteria, such as *Bacteroides* species, either cannot grow in the presence of oxygen or do not require oxygen to grow and are classified as either Gram-positive or Gram-negative.

Antibiotics that treat bacterial infections can be classified as broad-spectrum or narrow-spectrum. Antibiotics that are active against a mixture of Gram-positive, Gram-negative and anaerobic bacteria are referred to as broad-spectrum. Antibiotics that are active only against a select subset of bacteria are referred to as narrow-spectrum. Because it usually takes from 24 to 72 hours from the time a specimen is received in the laboratory to definitively diagnose a particular bacterial infection, physicians may be required to prescribe antibiotics for serious infections without having identified the bacteria. As such, effective first-line treatment of serious infections requires the use of broad-spectrum antibiotics with activity against a broad range of bacteria at least until the bacterial infection can be diagnosed.

Many strains of bacteria have mutated over time and have developed resistance to existing drugs, resulting in infections that are increasingly serious or more difficult to treat. These drug-resistant pathogens have become a growing menace to all people, regardless of age, gender or socioeconomic background. They endanger people in affluent, industrial societies like the United States, as well as in less-developed nations. Gram-positive bacteria that have developed resistance to existing drugs include:

- *Streptococcus pneumoniae* that cause pneumonia, ear infections, bloodstream infections and meningitis;
- *Staphylococcus aureus* that cause skin, bone, lung and bloodstream infections; and
- *Enterococci* that are responsible for infections transmitted in healthcare settings.
- Gram-negative bacteria that have developed resistance to existing drugs include:
- *Escherichia coli* that cause urinary tract, skin and bloodstream infections;
- *Salmonella* and *Escherichia coli* that cause foodborne infections; and
- *Acinetobacter baumannii* , *Pseudomonas aeruginosa* and *Klebsiella* spp. that are responsible for infections transmitted in healthcare settings.

According to a September 2013 report of the CDC, each year in the United States, at least two million people acquire serious infections with bacteria that are resistant to one or more of the antibiotics designed to treat those infections. At least 23,000 people die each year as a direct result of these antibiotic-resistant infections, with many more dying from other conditions that are complicated by the occurrence of an antibiotic-resistant infection. These antibiotic-resistant infections add considerable and avoidable costs to the already overburdened U.S. healthcare system. In the same September 2013 report, the CDC noted that the total economic cost of antibiotic infections to the U.S. economy has been estimated to be as high as $20 billion in excess of direct healthcare costs. In addition, the CDC reported that, among all of the bacterial resistance problems, Gram-negative pathogens are particularly worrisome because they are becoming resistant to nearly all drugs that would be considered for treatment, with the most serious Gram-negative infections being healthcare associated and the most common pathogens being *Enterobacteriaceae* , *Pseudomonas aeruginosa* and *Acinetobacter* .

As such, at present, there is an acute need for new drugs to treat multidrug-resistant Gram-negative bacteria. Currently approved products, such as Merrem and Levaquin, are becoming increasingly ineffective against Gram-negative bacteria due to increasing resistance, limiting patients' treatment options, particularly for patients with multidrug-resistant infections, and few new therapeutic agents are in clinical development.

A survey of infectious disease specialists published in the June 2012 edition of *Clinical Infectious Disease* rated multidrug-resistant Gram-negative infections as the most important unmet clinical need in current practice. In the survey, 63% of physicians reported treating a patient in the past year whose bacterial infection was resistant to all available antibacterial agents. As a further example of the seriousness of the threat of Gram-negative bacteria resistant to all available antibacterial agents, in 2014, the national media including *The Wall Street Journal* , *CBS* and *Fox News* reported on an outbreak, primarily in one suburban Chicago, Illinois hospital, of CRE with more than 40 cases reported in 2013. Additionally, in February 2015, an outbreak of CRE occurred at the Ronald Reagan UCLA Medical Center in which a total of seven people became infected and the infection was a contributing factor in the death of two patients. A similar report came from the Carolinas HealthCare System in February 2015, in which 18 people contracted CRE at a hospital in Charlotte, North Carolina and one person died. According to the CDC, CRE are a nightmare bacteria, are resistant to nearly all known antibiotics and kill up to 50% of people infected.

The growing issue of antibiotic-resistant bacterial infections has been widely recognized as an increasingly urgent public health threat, including by the World Health Organization, or WHO, the CDC and the Infectious Disease Society of America, or IDSA. In April 2014, the WHO issued an antimicrobial resistance global surveillance report stating that resistance to common bacteria has reached alarming levels worldwide indicating that many available treatment options are becoming ineffective, and leading to a negative impact in patient outcomes and health-care spending. The WHO warns that unless significant measures are taken, people will start to die from common, formerly treatable infections, and medical interventions such as surgery, chemotherapy, organ transplantation and care of premature infants will become increasingly risky. The important need for new treatment options for serious bacterial infections was further highlighted by the passage in the United States in July 2012 of the Generating Antibiotic Incentives Now, or GAIN, Act, which provides regulatory incentives for the development of new antibacterial or antifungal drugs intended to treat serious or life-threatening infections that are resistant to existing treatment. In September 2014, the United States' President's Council of Advisors on Science and Technology issued a report providing recommendations to combat the rise in antibiotic resistant bacteria and advising that without rapid action, the United States risks losing the tremendous progress made in antibiotic development over the last century. Their recommendations focused on three areas: improving surveillance, increasing longevity of current antibiotics and increasing the rate at which new antibiotics are discovered and developed.

Additionally, legislative initiatives have recently been introduced as part of the 21st Century Cures discussion document, including the Antibiotic Development to Advance Patient Treatment, or ADAPT, Act which would provide a pathway for approval of antibiotics in limited populations of patients with few or no suitable treatment options, the Developing an Innovating Strategy for Antimicrobial Resistant Microorganisms, or DISARM, Act which would designate certain novel antibiotics used to treat serious bacterial infections to receive higher Medicare reimbursement, and an amendment to the GAIN Act which would allow successful QIDP sponsors to transfer up to one year of exclusivity to another product, including products marketed by other companies.

Limitations of Available Treatment Options

When confronted with a new patient suffering from a serious infection caused by an unknown pathogen, a physician may be required to quickly initiate first-line empiric antibiotic treatment to stabilize the patient prior to definitively diagnosing the particular bacterial infection. However, current antibiotics for first-line empiric treatment of serious bacterial infections suffer from significant limitations, including one or more of the following:

Insufficient Coverage of Multidrug-resistant Bacteria. A physician cannot afford to be too limited in the spectrum of bacteria covered by antibiotics when initially treating a patient for a serious infection that has not yet been definitively identified. Frequently used products, such as Zyvox and Cubicin, are mostly limited to Gram-positive bacteria and thus are rarely used as a first-line empiric monotherapy if broad bacterial coverage is required. In addition, other popular antibiotics that have been used as first-line empiric monotherapies, such as Levaquin, piperacillin/tazobactam, which is marketed by Pfizer as Zosyn, carbapenems, such as Merrem, and imipenem/cilastatin, which is marketed by Merck as Primaxin, have seen their utility as first-line empiric monotherapies diminished as the number of bacterial strains resistant to these therapies has increased.

Safety and Tolerability Concerns. Concerns about antibiotic safety and tolerability are among the leading reasons why patients stop treatment and fail therapy. Antibiotics on the market have been associated with adverse effects such as myelosuppression, seizures, nephrotoxicity and gastrointestinal disorders.

Lack of Oral Dosage Forms to Permit Transition Therapy. When a patient comes to the emergency room or hospital for treatment of a serious infection, the patient initially receives IV treatment, which allows the drug to be delivered more rapidly and in a larger dose than oral treatment. Once the infection begins to respond to treatment and the patient is stabilized, depending on the infection, hospitals and physicians generally seek to minimize in-hospital treatment and, if possible, discharge patients from the hospital in order to reduce costs, avoid hospital-acquired infections, and improve the patients' quality of life. Upon discharge, physicians typically prefer to prescribe transition therapy treatment with an oral formulation of the same antibiotic. A transition therapy to oral treatment allows for more convenient and cost-effective out-patient treatment, with the oral antibiotic providing enhanced patient comfort and mobility and avoiding the risk of infection from the IV catheter. In addition, the use of the same antibiotic allows the physician to avoid switching the patient from the antibiotic that has proven effective during IV administration to a different antibiotic that may be less effective and carries the risk of new or different side effects. Many of the antibiotics that are most commonly used as first-line empiric monotherapies are only available in an IV formulation. Very few, if any, of the antibiotics that cover or are focused on the treatment of Gram-negative bacteria, including NTM, have oral dosage forms.

Given these limitations, there is an unmet medical need for a first-line empiric antibiotic treatment that has the following characteristics:

- Potency and effectiveness against a broad spectrum of bacteria, including NTM, multidrug-resistant Gram-negative, Gram-positive, atypical and anaerobic bacteria;
- Capability of being used as a monotherapy in the majority of patients in the hospital with cIAI, cUTI and other multidrug-resistant infections;
- A convenient dosing regimen, such as once or twice-daily;
- A favorable safety and tolerability profile; and

- Availability in an oral dosage form.

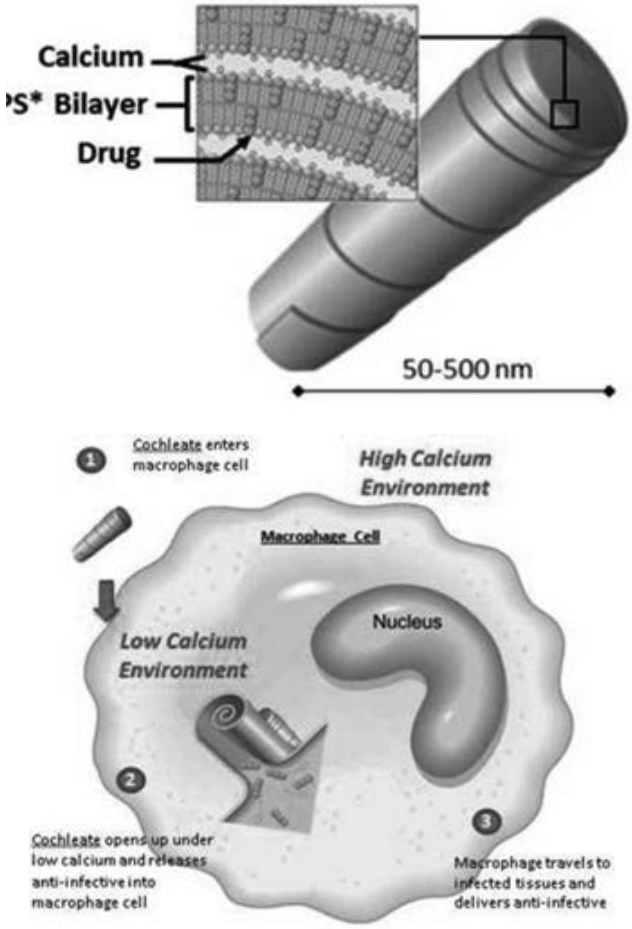
Our Cochleate Delivery Technology

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 are focused on the delivery of several potent and highly efficacious anti-fungal and anti-bacterial agents which, unfortunately, are currently still associated with serious side effects, including irreversible toxic effects on kidney and hearing function. Our technology may allow for the safe and targeted delivery of these agents, which positions us to be at the forefront of dealing with these very serious problems.

Our lipid-based delivery technology is currently being used to encapsulate potent but dangerous anti-infective drugs in tiny lipid-crystals which are selectively picked up by macrophage cells 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, the sensitive-organ exposure to these medications is believed to be drastically reduced, as well as the toxic side-effects. In summary, this unique technology offers (1) targeted delivery, (2) sensitive organ protection, and (3) oral formulation (even for IV-only medications).

Our cochleate delivery technology is based upon components which are believed to be non-toxic. The primary chemical components of our cochleate delivery technology are soy-derived phosphatidylserine, or "PS", and calcium, which are naturally occurring materials classified as generally recognized as safe, or GRAS, by the FDA. Our technology involves combining and mixing the soy-derived PS and calcium through a self-assembly process under carefully controlled conditions to envelop the subject drug into very small lipid-crystal particles. The result is a nano-size encochleated drug formulation. The unique cochleate structure protects the drug from degradation when it passes through the gastrointestinal (GI) tract and into the blood stream. The strong structure of the cochleate protects the drug as it travels through the GI tract. Once the cochleate, with the drug inside, is absorbed through the GI tract, it is engulfed by the target cells in the bloodstream, including cells called macrophages, and taken to the infected cells. Once the encochleated drug is engulfed by the macrophage, the lower calcium levels inside the macrophage compared to the high level of calcium outside the macrophage triggers the cochleate to open, thus releasing the drug.

COCHLEATE FORMULATION



* Phosphatidylserine.

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 our circulatory systems, thus still exposing our vulnerable organs and tissues to toxic effects of often potent medications. Keeping 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.

Historical Development of Cochleate Delivery Technology

The cochleate delivery technology was originally developed by the University of Medicine and Dentistry of New Jersey and Albany Medical College in collaboration with BioDelivery Sciences, Inc., a company founded in 1995 by Drs. Raphael Mannino, who joined our Scientific Advisory Board in connection with Aquarius acquisition, and Susan Gould-Fogerite, and others. BioDelivery Sciences International, Inc. (NASDAQ: BDSI) acquired BioDelivery Sciences, Inc. in 2002 and Drs. Mannino and Gould-Fogerite joined BDSI's management team. BDSI continued the development of the cochleate delivery technology pursuant to an exclusive license with the University of Medicine and Dentistry of New Jersey and Albany Medical College and application of such drug delivery technology to an array of established pharmaceutics, including an application of cochleate delivery technology to a broad spectrum anti-fungal drug called amphotericin B, which has developed into our MAT 2203 product candidate. BDSI filed an IND for this product at the end of 2006, performed several animal toxicology studies and performed a single dose Phase 1 study. In the animal studies conducted by BDSI, doses used in toxicology studies were shown to produce measureable tissue concentrations and efficacy against the fungal infections candidiasis and aspergillosis. In 2009, BDSI reported preliminary results from its Phase 1 study, where BDSI indicated that plasma concentrations of amphotericin B were detected in the sample of patients tested suggesting oral absorption from the cochleate delivery system. Forty-eight healthy volunteers participated in the study, with sixteen recruited for each of three dose groups. In each dose group, twelve volunteers received a single dose of cochleate amphotericin B (MAT 2203) and four received a placebo. Amphotericin B plasma concentrations were measured over a period of fourteen days. The study identified doses that were well-tolerated with no meaningful changes in laboratory safety values including those associated with renal function. The preliminary pharmacokinetic evaluation, available in February 2009, revealed that plasma concentrations were comparable to those seen in prior animal toxicology studies using the same formulation. In previous animal studies conducted by BDSI, doses used in toxicology studies were shown to produce measureable tissue concentrations and efficacy against the fungal infections candidiasis and aspergillosis.

Additional Pipeline Opportunities

We believe our cochleate delivery technology can be used to reformulate a wide variety of drugs which are currently only available in IV formulations. Leveraging our cochleate delivery technology, we believe we can develop a robust pipeline of product candidates. We have tested a range of pharmaceutical compounds reformulated by our cochleate delivery technology in proof-of-concept animal studies, including vaccines, curcumin, capreomycin, and atovaquone. By way of example, we recently received a patent issuance related to cochleate 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.

Our Cardiovascular Therapeutic Candidates

MAT9001

Our legacy 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.

On October 20, 2014, we submitted an IND to FDA for MAT9001 with an initial indication for the treatment of severe hypertriglyceridemia (TG>500 mg/dL). In the fourth quarter of 2014, we received feedback from FDA with respect to its IND submission for MAT9001. Although FDA did not raise any clinical hold issues, FDA provided recommendations for certain revisions to our planned four-week rat comparative bridging toxicity study as well as our planned 4-way crossover single dose Fed/Fast PK study of MAT9001 in comparison to another omega-3 product. Based on FDA's comments, during the first quarter of 2015, we submitted modified protocols for the four-week rat comparative bridging toxicity study, as well as our 4-way crossover single dose Fed/Fast PK study.

In June of 2015 we announced data from a PK/PD study that showed MAT9001 demonstrated superiority versus Vascepa® (icosapent ethyl) in reducing lipids, triglycerides, apolipoproteins and PCSK9 levels. The data were based on a pharmacokinetic and pharmacodynamics, open-label crossover study designed to compare the bioavailability and effects of MAT9001 versus Vascepa, ethyl ester of eicosapentaenoic acid (EPA), which was approved by the U.S. Food and Drug Administration in 2012 as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

Results and Trial Design

MAT9001 achieved a greater median percentage reduction from baseline to trial end in total cholesterol and a significantly greater median percentage reduction in four of six lipid measures, including total cholesterol, when compared to Vascepa:

- MAT9001 reduced median TG levels by 33.2 percent compared to 10.5 percent for Vascepa (P-Value <0.001);
- MAT9001 reduced median VLDL-C (very low density lipoprotein cholesterol) levels by 32.5 percent compared to 8.1 percent for Vascepa (P-Value <0.001);
- MAT9001 reduced median non-HDL-C (non-high-density cholesterol) levels by 8.8 percent compared to 4.6 percent for Vascepa (P-Value = 0.027);
- MAT9001 reduced median HDL-C (high-density cholesterol) levels by 11.3 percent compared to 11.1 percent for Vascepa (P-Value = 0.337);
- MAT9001 reduced median LDL (low-density lipoprotein cholesterol) levels by 2.4 percent compared to 4.3 percent for Vascepa (P-Value = 0.116);
- MAT9001 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 reduced median apolipoprotein AI levels by 15.3 percent compared to 10.2 percent for Vascepa (P-value = 0.003);
- MAT9001 reduced median apolipoprotein CIII levels by 25.5 percent compared to 5 percent for Vascepa (P-Value = 0.006);
- MAT9001 reduced median PCSK9 levels by 12.3 percent compared to an 8.8 percent increase in PCSK9 levels for Vascepa (P-Value <0.001).

The comparator study was conducted in 42 patients with high triglyceride levels. Study subjects had fasting TG levels of 200 to 400 mg/dL without lipid altering therapy, or fasting TG levels of 200 to 350 mg/dL if they were on a stable-dose statin monotherapy. 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, then washed out over five weeks, and then crossed over to Vascepa or MAT9001 for 14 days. Forty patients completed the trial.

MAT9001 met its primary endpoint 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). Vascepa is indicated for use with a lipid-lowering diet to reduce very high triglycerides in adult patients and is a trademark of Amarin Pharmaceuticals Ireland Ltd.

Following our acquisition of Aquarius Biotechnologies, Inc. in 2015, we made a strategic decision to focus our resources on the further development of our cochleate lipid-crystal nanoparticle delivery platform and products based on that technology. As a result, we are currently exploring strategic opportunities and partnerships for the continued development of MAT9001, both in the U.S. and abroad.

Exclusive License Agreement with Rutgers University

Through our acquisition of Aquarius, 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.

Exclusively Licensed Intellectual Property Relating to Our Proprietary Cochleate Delivery Technology Platform and MAT2203 and MAT2501

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 cochleates and formulate the active pharmaceutical ingredients delivered inside this delivery technology, as in MAT2203 and MAT2501. Pursuant to our license agreement, we have acquired rights to a portfolio of 18 issued and foreign patents, including 11 patents issued within the last 3 years, which extends patent protection until at least 2033. In addition, we have more than 20 pending patent applications filed both in the United States and in foreign jurisdictions, including 16 national phase applications filed within the past 2 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 at least 2033. The patent portfolio covering our cochleate delivery system 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, 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.”

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 technology platform 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. Although we believe that our formulation 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 payors.

Competition for MAT2203 for treatment of severe fungal infections

We believe that our key competitors in the treatment of severe fungal infections, such as invasive candidiasis and aspergillosis, are as follows:

- Pfizer, the manufacturer of Vfend (voriconazole) and Eraxis (anidulafungin), as well as the generic manufacturers of voriconazole;
- Merck, the manufacturer of Noxafil (posaconazole) and Cancidas (caspofungin);
- Astellas, the manufacturer of Mycamine (micafungin) and the marketer of Cresemba (isavuconazonium); and
- Gilead, the manufacturer of AmBisome B (liposomal amphotericin B).

There are also a number of smaller companies working to develop new drugs and other therapies for fungal infections that are undergoing clinical trials. The key competitive factors affecting the success of all of our product candidates are likely to be their efficacy, safety, convenience and price.

Competition for MAT2501 for the treatment of multi-drug resistant gram negative bacteria

We intend to develop MAT2501 as a broad spectrum, oral antibiotic for the treatment of multi-drug resistant infections, including both chronic and acute bacterial infections, such as nontuberculous mycobacterium (NTM) and multi-drug resistant gram-negative infections. If approved, MAT2501 would compete with a number of drugs currently in development, including Arikayce®, an inhaled version of amikacin being developed by Insmed Incorporated for the treatment of NTM; plazomycin, which is being developed by Achaogen, Inc.; eravacycline, which is being developed by Tetraphase Pharmaceuticals, Inc.; Brilacidin®, being developed as a broad spectrum anti-bacterial by Cellceutix Corporation and Raptor Pharmaceuticals, Inc., which has recently announced it intends to pursue development of an inhaled version of the antibiotic levofloxacin for the treatment of NTM.

Manufacturing

We currently lease and operate limited in-house manufacturing capabilities for our product candidates, including MAT2203 and MAT2501. While sufficient to produce the clinical supplies of product necessary to conduct our ongoing clinical trials, these are short term arrangements and we currently do not have sufficient manufacturing facilities on a long term basis for the production of clinical or commercial quantities of any of our product candidates. If we are not able to retain our current manufacturing facilities and if we do not develop an in-house manufacturing capability for cochleates needed for our MAT2203 and MAT2501 product candidates sufficient to produce product for continued development and then commercialization of these products, we will need to develop relationships with third-party manufacturers for the manufacture of our product candidates which is likely to be time consuming and expensive.

There are a number of potential third party suppliers for amphotericin B and amikacin, the generic active pharmaceutical ingredients in our lead clinical stage product candidates – MAT2203 and MAT2501, respectively. Although to date we have not entered into supply agreements to secure sufficient supply of amphotericin B and amikacin to support our clinical programs for MAT2203 and MAT2501, we believe we will be able to secure supply of amphotericin B and amikacin to support our clinical programs for MAT2203 and MAT2501 from one or more third-party suppliers. As we move through development for each of our product candidates, we expect to enter into long term supply arrangements for these 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, the 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 the 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 the FDA and the Department of Justice, or DOJ, or other governmental entities.

Our product candidates must be approved by the 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 the FDA's good laboratory practice, or cGLP, regulations;
- submission to the 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 the 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 the 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 GLP 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 the 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 the FDA as part of the IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the 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 the FDA must resolve any outstanding concerns before the clinical trial can begin. Accordingly, submission of an IND may or may not result in the 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. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA or IND so long as the clinical trial is conducted in compliance with an international guideline for the ethical conduct of clinical research known as the Declaration of Helsinki and/or the laws and regulations of the country or countries in which the clinical trial is performed, whichever provides the greater protection to the participants in the clinical trial.

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

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

Phase 2 : The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance 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 the 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 the 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, the 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. The 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 the 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 the 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, currently exceeding $2.3 million, and the sponsor of an approved NDA is also subject to annual product and establishment user fees, currently exceeding $114,000 per product and $585,000 per establishment. These fees are typically increased annually.

The FDA conducts a preliminary review of an NDA within 60 days of its receipt and informs the sponsor by the 74th day after the FDA's receipt of the submission whether the application is sufficiently complete to permit substantive review. The 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 the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The 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 the FDA for various reasons, including for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the 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. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The 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. The 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

The 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, the 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 the FDA and the 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 the 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 the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the 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 the FDA if the 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. The 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, the 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. The 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 the FDA's goal for taking action on a marketing application from ten months to six months.

Under Section 524 of the FDCA, the 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. The 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

The 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. The 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. The 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 the 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 the FDA.

The FDA's Decision on an NDA

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

If the 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, the 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, the 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. The 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.

The 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 the 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 the FDA and state agencies, and are subject to periodic unannounced inspections by the 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, the 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 the 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.

The 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. The 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 the FDA to approve generic drugs that are the same as drugs previously approved by the 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, the 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, the 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, the 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, the 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, the 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 the 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 the 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 the FDA, the applicant is required to certify to the 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 the 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 the 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 the 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, the FDA and the FDA's internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

The 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 the 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 the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the 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 the FDA cannot approve another application.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the 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, the 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 the 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.

Other Health Care Regulations

Health Privacy Laws

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH Act"), require health care plans, health care providers and health care clearinghouses, collectively defined under HIPAA as "Covered Entities," to comply with standards for the use and disclosure of health information within such organizations and with third parties. These include standards for:

- Common health care transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures;
- Unique identifiers for providers, employers, health plans and individuals; and
- Security and privacy of health information.

Although the obligations of HIPAA only apply directly to Covered Entities, any Covered Entity that uses third parties (referred to in HIPAA as "Business Associates") to perform functions on its behalf involving the creation or use of certain patient health information is required to have a contract with the Business Associate that limits the use and disclosure of such information by the Business Associate.

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.

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 new 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 the FDA. A drug sponsor may request the FDA to designate its product as a QIDP any time before the submission of an NDA. The 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 the FDA and can qualify for "fast track" status.

The additional five years of market exclusivity under the GAIN Act for drug products designated by the 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 the 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 the 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 the 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 the 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 federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, 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 Health Information Technology for Economic and Clinical Health Act 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 Patient Protection and Affordable Care Act 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 30, 2016, we had 10 full-time employees.

Research and Development

For the years ended December 31, 2014 and December 31, 2015, we spent approximately $5.2 million and $5.3 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 support of our MAT9001 program which we are no longer actively pursuing and our anti-infective product candidates, MAT2203 and MAT2501.

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 Aquarius Biotechnologies 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. entered into entered into a merger agreement (the "2013 Merger Agreement") with Matinas Merger Sub, Inc., a Delaware corporation and our wholly owned subsidiary, or Merger Sub. Pursuant to the terms of the 2013 Merger Agreement, as a condition of and contemporaneously with the initial closing of the 2013 Private Placement, Merger Sub merged (the "2013 Merger") with and into Matinas BioPharma and Matinas BioPharma became a wholly owned subsidiary of ours. After consummation of the Merger transaction, the management of Matinas BioPharma became the management of Holdings and the board representatives consisted of four former Board members of Matinas BioPharma and Mr. Adam Stern as the Aegis Capital Corp. nominee. Because Holdings was formed solely to effect the 2013 Merger and the 2013 Private Placement, with no operations, and assets consisting solely of cash and cash equivalents, we accounted for the 2013 Merger as a reverse acquisition. The legal acquirer Matinas BioPharma becomes the successor entity, and its historical results became the historical results for Holdings (the legal acquirer and the registrant). On January 29, 2015, we acquired Aquarius Biotechnologies Inc.

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

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

Item 1A. Risk Factors

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

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 $9.1 million and $10.2 million for the years ended December 31, 2015 and 2014, respectively. As of December 31 2015, we had an accumulated deficit of $23.2 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 primarily through private placements 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 research and development, including preclinical studies and, beginning in 2014, clinical trials. 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 ourstockholders' deficit and working capital. We anticipate that our expenses will increase substantially if and as we:

- initiate our planned Phase 2a clinical trial of MAT2203, our lead product candidate;
- initiate and continue the research and development of our other product candidates and potential product candidates, including MAT2501;
- seek to discover and develop additional product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure in the future to commercialize any products for which we may obtain regulatory approval;
- 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 unless and 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.

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern, and as a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2015 with respect to this uncertainty. This going concern opinion, and any future going concern opinion, could materially limit our ability to raise additional capital. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. To date, we have devoted our resources to developing MAT9001 and our lead anti-infective product candidates, MAT2203 and MAT2501 and other product candidates developed from our cochleate delivery technology platform, but none of these product candidates can be marketed until regulatory approval has been obtained. Meaningful revenues will likely not be available until, and unless, MAT2203 or any of our other product candidate is approved by the FDA or comparable regulatory agencies in other countries and successfully marketed, either by us or a partner. The perception that we may not be able to continue as a going concern may cause potential partners or investors to choose not to deal with us due to concerns about our ability to meet our contractual and financial obligations.

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 the planned Phase 2a clinical trial of MAT2203 and advance MAT2501 into clinical development, 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. 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 of approximately $3.2 million as of December 31, 2015, will enable us to fund our operating expenses and capital expenditure requirements through July 2016. 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 planned Phase 2a clinical trial of MAT2203;

- the scope, progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, other product candidates, including MAT2501, and any future product candidates;
- 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 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, 2015, we had outstanding options to purchase an aggregate of 6,093,000 shares of our common stock at a weighted average exercise price of $0.93 per share and warrants to purchase an aggregate of 39,250,000 shares of our common stock at a weighted average exercise price of $1.18 per share. The exercise of such outstanding options and warrants will result in dilution of the value of our shares. In addition, pursuant to the terms of the merger agreement with 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 limited operating history 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 have a limited operating history. 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.

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

Our research and development of product candidates is primarily focused on the identification of product candidates for the treatment of human fungal and bacterial infections. Our approach is unproven and we do not know whether we will be successful in our efforts to use our cochleate delivery platform to build a pipeline of product candidates or if we will be able to develop any products of commercial value.

Our scientific approach to the development of anti-infective medicines focuses on using our proprietary technology to deliver therapies for the treatment of human fungal and bacterial infections. Any product candidates that we develop may not be effective and we may not be successful in using our cochleate delivery platform to build a pipeline of anti-infective medications and progress these product candidates through clinical development for the treatment of any medical conditions.

Even if we are successful in continuing to build our pipeline, we may not be able to develop product candidates that are safe and effective. Our research programs may initially show promise in creating potential product candidates, yet fail to yield viable product candidates for further clinical development for a number of reasons, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. Our research programs to identify new product candidates will require substantial technical, financial and human resources. In addition, we may focus our efforts and resources on one or more potential product candidates that ultimately prove to be unsuccessful. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price.

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

We expect to invest most of our capital in the development of MAT2203, MAT2501 and other product candidates derived from our cochleate delivery platform technology. Our ability to generate revenue related to product sales, which we do not expect will occur for at least the next several years, if ever, will depend on the successful development and regulatory approval of one or more of our product candidates. All of our product candidates require regulatory review and approval prior to commercialization. Any delays in the regulatory review or approval of our product candidates would delay market launch, increase our cash requirements and result in additional operating losses. This failure to obtain regulatory approvals would prevent our product candidate from being marketed and would have a material and adverse effect on our business.

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

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

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

We depend 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 completely on the cochleate delivery platform technology that we have licensed from Rutgers. The loss of our key technologies would seriously 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 1 clinical studies for MAT2203 do not ensure that our Phase 2a trial 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 the Phase 2a clinical trial for MAT2203, or any other future clinical trials for 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. The Phase 2a clinical trial for MAT2203 is being conducted in cooperation with and funded by the NIH and as a result can be delayed by the NIH for many reasons, including changing priorities in the NIH or other factors outside our control.

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 MAT2203 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 force the NIH to commence or complete planned clinical studies, despite the existence of contractual agreements;
- 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 cochleates needed for our MAT2203 and MAT2501 product candidates. If we do not develop a long term in-house manufacturing capability for the cochleates needed for our MAT2203 and MAT2501 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 not successful in discovering, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.

A key element of our strategy is to leverage our cochleate drug delivery technology platform to discover, develop and commercialize a portfolio of product candidates. We are seeking to do so through our internal research programs and are exploring, and may also explore in the future, strategic partnerships for the development of new products. Other than MAT2203 and MAT2501, all of our other potential cochleate-related product candidates remain in the discovery and preclinical stages.

Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- the research methodology used may not be successful in identifying potential product candidates;
- we may be unable to identify viable product candidates in our screening campaigns;
- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors; and
- the development of bacterial resistance to potential product candidates may render them ineffective against target infections.

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 MAT2203, MAT2501 or any other product candidates we may develop, we still may not be able to successfully commercialize it and the revenue that we generate from its sales, if any, may be limited.

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

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

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

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

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

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

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

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

If we are not successful in recruiting sales and marketing personnel or in building a sales and marketing infrastructure, or if we do not successfully enter into appropriate collaboration arrangements, we will have difficulty successfully commercializing MAT2203, MAT2501 or any other product candidates we may develop, which would adversely affect our business, operating results and financial condition. Outside the United States, we may commercialize our product candidates by entering into collaboration agreements with pharmaceutical partners. We may not be able to enter into such agreements on terms acceptable to us or at all. In addition, even if we enter into such relationships, we may have limited or no control over the sales, marketing and distribution activities of these third parties. Our future revenues may depend heavily on the success of the efforts of these third parties

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. Established competitors may invest heavily to quickly discover and develop novel compounds that could make MAT2203, MAT2501 or any other product candidates we may develop obsolete or uneconomical. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to MAT2203, MAT2501 or any of our other product candidates. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. We face competition with respect to our current product candidates and we will face competition with respect to any product candidates that we may seek to develop or commercialize in the future. Our current and potential competitors in the anti-fungal marketplace for which we are developing MAT2203 include Merck & Co. Inc., Astellas Pharma US, Pfizer, Inc., Novartis AG, Viamet Inc., Cidara Therapeutics and Sigma Tau. With respect to competition for MAT2501 in the anti-bacterial marketplace, our current and potential competitors include Insmed Incorporated, Merck & Co., Tetraphase Pharmaceuticals, Inc., Achaogen, Inc., Raptor Pharmaceuticals and The Medicines Company.

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

Even if we obtain United States regulatory approval of MAT2203, MAT2501 or any other product candidates that we may develop, the 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 the 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.

The 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. The 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 the 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. The 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. The 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 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.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

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 that could prevent or delay marketing approval for our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any of our future products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidate1, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

In the United States, the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for MAT2203, MAT2501 or any other product candidates that we may develop and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 or, collectively, the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Health Care Reform Law revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners, and incur substantial costs to ensure compliance.

In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability.

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 MAT 2203, MAT2501 or any other product candidates that we may develop in foreign markets, we would be subject to additional risks and uncertainties, including:

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

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

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

The 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 subject to challenge under one or more of these laws.

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 Health Care Reform Law, 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 Health Care Reform Law 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 our product candidates, which exposes us to the risk of reliance on the performance of third parties.

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

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

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

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

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, and government purchasers. 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.

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 are highly dependent on our cochleate delivery technology platform which is licensed to us by Rutgers. We do not own the patents that underlie 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 sublicensees 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 eighteen 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 MAT2203, MAT2501 or any future product candidate. There may be certain issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize MAT2203 or MAT2501 and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties against us would be time-consuming and may:

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

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

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

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 have obtained orphan drug designation for MAT2501 for the treatment of nontuberculous mycobacteria and 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. The applicable 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 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 may be eligible for designation of certain of our product candidates as qualified infectious disease products, or 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 ten 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 Roelof Rongen, our President and CEO, or Jerome D. Jabbour, our President, or Raphael J. Mannino, our Chief Technology Officer, would adversely impact our business prospects.

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

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

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

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

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

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

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

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

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

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

Risks related to our common stock

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. 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.

There has been a limited trading market for our common stock and there has been limited market activity to date.

Currently, our common stock is available for quotation on the OTCQB under the symbol “MTNB” and there has been limited market activity to date.. It is anticipated that there may continue to be a limited trading market for our common stock on the OTCQB. 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. 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, 2015 through March 15, 2016, the market price of our common stock has fluctuated from a high of $1.42 per share to a low of $0.34 per share. 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.

Our shares are subject to the penny stock rules, which may make it more difficult to sell our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00 (other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system). The OTCQB does not meet such requirements and if the price of our common stock is less than $5.00, our common stock will be deemed penny stocks. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that prior to effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser’s written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stock holders may have difficulty selling their shares.

FINRA sales practice requirements may also limit your ability to buy and sell our common stock, which could depress the price of our shares.

FINRA rules require broker-dealers to have reasonable grounds for believing that an investment is suitable for a customer before recommending that investment to the customer. Prior to recommending speculative low-priced securities to their non-institutional customers, broker-dealers must make reasonable efforts to obtain information about the customer’s financial status, tax status and investment objectives, among other things. Under interpretations of these rules, FINRA believes that there is a high probability such speculative low-priced securities will not be suitable for at least some customers. Thus, FINRA requirements make it more difficult for broker-dealers to recommend that their customers buy our common stock, which may limit your ability to buy and sell our shares, have an adverse effect on the market for our shares, and thereby depress our share price.

You may face significant restrictions on the resale of your shares due to state “blue sky” laws.

Each state has its own securities laws, often called “blue sky” laws, which (1) limit sales of securities to a state’s residents unless the securities are registered in that state or qualify for an exemption from registration, and (2) govern the reporting requirements for broker-dealers doing business directly or indirectly in the state. Before a security is sold in a state, there must be a registration in place to cover the transaction, or it must be exempt from registration. The applicable broker-dealer must also be registered in that state.

We do not know whether our securities will be registered or exempt from registration under the laws of any state. A determination regarding registration will be made by those broker-dealers, if any, who agree to serve as market makers for our common stock. We have not yet applied to have our securities registered in any state and will not do so until we receive expressions of interest from investors resident in specific states after they have viewed this Annual Report. There may be significant state blue sky law restrictions on the ability of investors to sell, and on purchasers to buy, our securities. You should therefore consider the resale market for our common stock to be limited, as you may be unable to resell your Shares without the significant expense of state registration or qualification.

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" for up to five years, 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 particularly 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" and if we are no longer a smaller reporting company at such time, 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.

We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs

We have had material weaknesses in our internal control over financial reporting in the past and may be unable to maintain effective control over financial reporting.

Prior to February 2014, we had not been a public reporting company and have had limited accounting personnel and systems to adequately execute accounting processes and limited other supervisory resources with which to address internal control over financial reporting. We and our independent registered public accounting firm identified material weaknesses in internal control over financial reporting for the years ended December 31, 2013 and 2012 related (i) financial closing procedures and lack of sufficient resources to maintain financial records and account for significant accounting transactions, particularly related to equity transactions and restricted stock and stock options for employees and non-employees and (ii) lack of proper segregation of duties. We have implemented and controls, which we believe have remediated these material weaknesses and underlying deficiencies. Amongst other actions, we have recently added a senior accountant to our finance team; commenced implementation of enhanced review procedures; and begun a comprehensive documentation of our accounting policies and our internal controls and procedures. We have also hired an accounting firm to provide technical accounting support and an additional level of review.

Under standards established by the Public Company Accounting Oversight Board, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. 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 our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. We cannot assure that there will not be additional material weaknesses and significant deficiencies that our independent registered public accounting firm or we will identify. If we identify such issues or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected and we may be unable to maintain compliance with applicable securities laws and listing requirements. See Item 9A for our evaluation of our disclosure controls and procedures.

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.

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.

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 to the stockholders of common stock 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 10,000,000 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 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 the 2013 Merger (as defined herein), our ability to utilize our federal net operating loss, carryforwards and federal tax credit 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, 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 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 United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Facilities

Our principal facilities 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 small laboratory spaces in Monmouth Junction, NJ, Somerset, NJ and Bridgewater Township, NJ.

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

Prior to July 21, 2014, no public trades occurred in our common stock. On July 21, 2014, our common stock commenced quotation on the OTCQB under the symbol "MTNB". The following table sets forth, for the periods indicated, the reported high and low closing 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.

	Fiscal Year 2014	
	High	Low
Third Quarter (1)	$ 1.35	$ 0.59
Fourth Quarter	$ 0.80	$ 0.31

(1) From July 21, 2014

	Fiscal Year 2015	
	High	Low
First Quarter	$ 0.65	$ 0.34
Second Quarter	$ 1.42	$ 0.60
Third Quarter	$ 1.05	$ 0.73
Fourth Quarter	$ 0.91	$ 0.60

Holders

As of March 24, 2016, we had approximately 322 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 not paid any cash dividends to date, nor do we anticipate paying any cash dividends in the foreseeable future. For the foreseeable future, we intend to retain all of our earnings, if any, to finance our growth and operations and to fund the expansion of our business. Payment of any dividends will be made in the discretion of our Board of Directors, after its taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion. 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 common stock.

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, 2015.

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 identifying and developing safe and effective broad spectrum therapeutics for the treatment of serious and life-threatening infections. We are developing a balanced and broad pipeline of product and development candidates, with an initial focus on serious fungal and bacterial infections. On January 29, 2015, we completed the acquisition of Aquarius Biotechnologies Inc., (referred to as the "Aquarius Merger" throughout this document), a New Jersey-based, early-stage pharmaceutical company focused on the development of differentiated and orally delivered therapeutics based on a proprietary, lipid crystal drug delivery platform called "cochleate delivery technology".

Our proprietary cochleate delivery technology platform, licensed from Rutgers University on an exclusive worldwide basis, is designed specifically for the targeted and safe delivery of pharmaceuticals directly to the site of infection or inflammation. This innovative technology utilizes lipid-crystal nano-particle cochleates to nano-encapsulate existing drugs, which is designed to make them safer, more tolerable, less toxic and orally bioavailable. We believe this platform represents a significant innovation that may result in meaningful improvements to currently available therapies to treat numerous life-threatening diseases, including serious fungal infections, NTM infections and multi-drug resistant, or MDR, gram-negative bacterial infections.

Currently, we are focused on the anti-infectives market and on drug candidates which demonstrate the value and innovation associated with our unique delivery platform technology. We believe initially focusing on the anti-infectives market has distinct advantages for the development of products which meet significant unmet medical need, including:

- a current regulatory environment which provides small development and clinical stage companies incentives and opportunities to reduce development cost and timeline to market for anti-infective drug candidates;
- traditional high correlation between efficacy and safety data in preclinical animal models and the outcome of human clinical trials with these product candidates;
- attractive commercial opportunities for a product differentiated in its safety profile, mode of action and oral bioavailability positioned against current therapies with significant side effects, limited efficacy and intravenous delivery resulting in lack of convenience, compliance and at a significant burden to the cost of healthcare; and
- an ability to commercialize anti-infective products with a focused and cost-efficient sales and marketing organization

We currently have two clinical-stage products designed for the treatment of infectious disease. Our lead product candidate is MAT 2203, a novel oral formulation of a broad spectrum anti-fungal drug called amphotericin B which uses our cochleate delivery technology. We are initially developing MAT2203 for the treatment of Candida infections. A Phase 1a study has been completed and demonstrated that MAT2203 was generally well tolerated at all dosage levels with no serious adverse events reports and no laboratory or renal function abnormalities observed. We are currently screening and enrolling patients in a Phase 2a study of MAT2203 in collaboration with the National Institute of Allergy and Infectious Diseases, or NIAID, of the National Institutes of Health, or NIH, and, assuming the NIH meets the anticipated clinical timelines, we anticipate announcing results during 2016.

Our second clinical stage product candidate is MAT2501, an orally administered, encochleated formulation of the broad spectrum aminoglycoside antibiotic amikacin which may be used to treat different types of multidrug-resistant bacteria, including non-tubercular mycobacterial infections (NTM), as well as various multidrug-resistant gram negative and intracellular bacterial infections. Currently, amikacin cannot be absorbed enterally and must be given by intravenous, intramuscular or nebulization routes with the significant risk of nephrotoxicity and ototoxicity, which makes it an impractical choice when treating serious infections which often require long courses of therapy, often 12 to 18 months or longer. MAT2501, taking advantage of its innovative, nano-encapsulation delivery technology, is being developed to be orally administered, and is designed to be a safer and targeted therapy for improved treatment of these serious and life-threatening bacterial infections in patients, including those who are severely immunocompromised. We are initially developing MAT2501 for the treatment of non-tuberculous mycobacteria (NTM). NTM causes many serious and life-threatening diseases, including pulmonary disease, skin and soft tissue disease, joint infections and, in immunocompromised individuals, disseminated infection. The most common clinical manifestation of NTM disease is pulmonary, or lung, disease. NTM lung infection occurs when a person inhales the organism from their environment. There are about 50,000 to 90,000 people with NTM pulmonary disease in the United States, with a much higher prevalence in older adults, and these numbers appear to be increasing. However, NTM can affect any age group. Without treatment, the progressive lung infection caused by NTM results in severe cough, fatigue and weight loss, and ultimately can lead to death. In some people NTM infections can become chronic and require ongoing treatment. Treatment may be difficult because NTM bacteria may be resistant to many common types of antibiotics. Severe NTM lung disease can have a significant impact on quality of life and can be life-threatening. We are also developing MAT2501 for the treatment of a variety of serious and acute bacterial infections, including the treatment of gram negative bacterial infections, currently the most significant unmet medical need identified by infectious disease specialists. We recently filed an Investigational New Drug (IND) application with FDA and were cleared to commence Phase 1 clinical studies in January 2016. We plan to initiate the first Phase 1 study of MAT2501 during 2016.

We are currently exploring strategic partnering options for our legacy cardiovascular drug, MAT9001, which has been developed and targeted to date for the treatment of very high triglycerides and MAT8800, our discovery program seeking to identify product candidates derived from omega-3 fatty acids for the treatment of nan-alcoholic fatty liver disease.

We are a development stage company and have generated $.2 million in contract research revenues during 2015. These contract research revenues ended during 2015 and we do not anticipate any revenues during 2016. We have incurred losses for each period from inception. Our net loss was approximately $9.1 million and $10.2 million for the fiscal years ended December 31, 2015 and 2014, respectively. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We expect our expenses to increase significantly in connection with our ongoing activities to develop, seek regulatory approval and commercialization of MAT2203 and MAT2501 and any other product candidates we choose to develop based upon our platform technology. Accordingly, we will need additional financing to support our continuing operations. We will seek to fund our operations through public or private equity or debt financings or other sources, which may include collaborations with third parties. 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 fiscal 2015, we generated approximately $.2 million in contract research revenues resulting from the acquisition of Aquarius. Our ability to generate product revenue from our lead clinical product candidates, if approved, which we do not expect to occur before 2020, if ever, will depend significantly on the successful development and eventual commercialization of MAT2203 and MAT2501.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of MAT2203 and MAT2501 and, to a lesser extent, MAT9001, 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 for the years ended December 31, 2015 and 2014. 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, R&D employee costs (including stock option expenses), travel and medical education.

	Year Ended December 31,	
	2015	2014
	($ in thousands)	
Direct research and development expenses:		
Manufacturing process development	$ 419	$ 1,373
Preclinical trials	310	299
Clinical Development	1,406	955
Regulatory	353	413
Internal staffing, overhead and other	2,804	2,135
Total research & development	$ 5,292	$ 5,175

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.

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 be flat in 2016 due to the implementation of a cost savings steps, offset by 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.

Sale of Net Operating Losses (NOLs)

Constitutes income obtained from selling unused net operating losses (NOLs) and unused research tax credits under the New Jersey Technology Business Tax Certificate Program.

Other Income (expense), net

Other expense, 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, net of forfeitures. 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.

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 with a limited operating history, we utilized data from a representative group of companies to estimate expected stock price volatility. We selected companies from the biopharmaceutical industry with similar characteristics to us, including those in the early stage of product development and with a therapeutic focus.

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, 2015 and 2014 and to re-measure stock options issued to consultants.

	For the year ended December 31,	
	2015	**2014**
Volatility	71.1 – 102.3%	68.76%
Risk-free interest rate	1.34% - 1.74%	1.65% – 1.93%
Dividend yield	0.0%	0.0%
Expected life	6.0 years	4.75 – 5.5 years

The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as we have limited trading history for our common stock. We will continue to analyze the historical stock price volatility and 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.

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. We use historical data to estimate pre-vesting option forfeitures and record share-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised.

Share-based compensation expense associated with stock options, restricted stock granted to employees and non-employees was $1.6 million for 2015 and $2.0 million for 2014. As of December 31, 2015, we had $1.9 million of total unrecognized share-based compensation expense, which we expect to recognize over a weighted-average remaining vesting period of approximately 1.3 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.

We estimated the forfeiture rate at the time of grant and, if necessary, revised in subsequent periods if actual forfeitures differed from those estimates. Forfeitures were estimated based on management's expectation through industry knowledge and historical data.

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, 2015, there were 2,038,697 shares of our common stock available for issuance under the Plan.

As of December 31, 2015, we had outstanding options to purchase an aggregate of 6,903,000 shares of our common stock with a weighted average exercise price of $0.93. At December 31, 2015, 3,751,742 options had vested at a weighted average exercise price of $0.65 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, 2015. The total intrinsic value of options outstanding and vested at December 31, 2015 was $0.6 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, 2015 and 2014.

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.

Results of Operations

Comparison of Years Ended December 31, 2015 and 2014

	Year Ended December 31, 2015	2014	Increase (Decrease)
		(In thousands)	
Expenses:			
Research and development	$ 5,292	$ 5,176	$ 116
General and administrative	4,814	5,289	(475)
Operating Expenses	$ 10,106	$ 10,465	$ (359)

Research and Development expenses. Research and development (R&D) expense for the year ended December 31, 2015 was $5.3 million, compared to $5.2 million for the year ended December 31, 2014, an increase of $0.1 million. R&D expenses in total were comparable year over year; however, the areas in which we spent our resources changed. During 2015, we made a strategic decision to shift resources away from our legacy MAT9001 cardiovascular product and toward its two clinical stage anti-infective products, MAT2203 and MAT2501. In addition, we shifted our spending from manufacturing development to pre-clinical, clinical, regulatory and infrastructure expenses.

General and Administrative expenses. General and administrative expense for the year ended December 31, 2015 was $4.8 million compared to $5.3 million for the year ended December 31, 2014, a decrease of $0.5 million. The decrease in general and administrative expense was primarily due to decreased vendor stock based compensation expenses for services. During 2015, we saw an increase in insurance costs of approximately $0.1 million, related to premiums for liability coverage. In addition, we incurred approximately $0.1 million in transaction costs associated with the Aquarius Merger.

Sources of Liquidity

We have funded our operations since inception through private placements of our preferred stock and our common stock and common stock warrants. As of December 31, 2015, we have raised a total of $21.2 million in net proceeds from sales of our equity securities.

As of December 31, 2015, we had cash and cash equivalents totaling $3.2 million.

2015 Private Placement

In March and April 2015, we completed the 2015 Private Placement Funding which is detailed in our Financial Statement footnotes (Note E), under which we sold an aggregate of 20,000,000 shares of our common stock and warrants to purchase an aggregate of 20,000,000 shares of our common stock with an exercise price of $0.75 per share, which warrants are exercisable for a period of five years from the initial closing date. Aegis Capital Corp. acted as the Placement Agent for the 2015 Private Placement (the “Placement Agent”). The gross proceeds to us from the 2015 Private Placement were $10.0 million.

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, 2015	
	2015	**2014**
Cash used in operating activities	$ (7,815)	$ (7,961)
Cash used in investing activities	(5)	(289)
Cash provided by financing activities	8,456	-
Net increase/(decrease) in cash and cash equivalents	$ 636	$ (8,250)

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, G&A costs are incurred related to becoming a public company, personnel costs in the Finance and Executive area, as well as costs associated with legal and patent review. Net cash used in operating activities was approximately $7.8 million for the year ended December 31, 2015 and $8.0 million for the year ended December 31, 2014. In the event we are able to raise additional financing, we expect that there will be a significant increase in cash used in our research and development activities during the second half of 2016 as we continue to move our product candidates forward in their development cycle.

Investing Activities

Net cash used in investing activities was $5,000 for the year ended December 31, 2015 and $.3 million for the year ended December 31, 2014. The cash used in investing activities for the years ended December 31, 2015 and December 31, 2014 was primarily the purchase of scientific laboratory equipment.

Financing Activities

Net cash provided by financing activities was $8.5 million for the year ended December 31, 2015 and zero for the year ended December 31, 2014. The cash provided by financing activities for the year ended December 31, 2015 was primarily due to proceeds received from our 2015 Private Placement.

Funding Requirements and Other Liquidity Matters

MAT2203 and MAT2501 are still in development stages. 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:

- initiate our planned Phase 2a clinical trials of MAT2203, our lead product candidate;
- initiate and continue the research and development of our other product candidates and potential product candidates, including MAT2501;
- seek to discover and develop additional product candidates using our cochleate lipid-crystal platform delivery technology, ;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;

- establish a sales, marketing and distribution infrastructure in the future to commercialize any products for which we may obtain regulatory approval;
- 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 will only be sufficient to fund our operating expenses and capital expenditures requirements through July 2016. We will need additional financing to fund our operating expenses and to initiate and conduct our intended clinical programs, file additional patent applications and enhance our intellectual property position for lead compounds, and prepare for submission of an NDA for MAT2203 and MAT2501, and potentially conduct preclinical work in order to identify product candidates utilizing our cochleate delivery platform technology. We have based this estimate on assumptions that may prove to be wrong in the future, and we may use our available capital resources sooner than we currently expect. Unless we obtain additional financing, there is substantial doubt we can continue as a going concern.

Until the time we can generate substantial product revenues from commercializing MAT2203, MAT2501 or any future product candidates, if ever, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, 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 and could increase our expenses and require that our assets secure such debt. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds 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 any product candidates under our development that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

On November 1, 2013, we entered into a seven year lease for office space in Bedminster, New Jersey. The commencement date and first obligation to pay rent was June 2014, with annual rent beginning at approximately $.1 million per year, increasing to $.2 million in the final year.

In December 2015, the Company renewed an agreement to lease laboratory space for one year commencing January 1, 2016 in Monmouth Junction, New Jersey. Base rent for the year ended December 31, 2016 will be approximately $27,000.

We may enter into contracts in the normal course of business with clinical research organizations for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination on notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Through our acquisition of Aquarius, 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) 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.

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

Evaluation of Disclosure Controls and Procedures.

As of December 31, 2015, we evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness 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 are effective at the reasonable assurance level as of December 31, 2015. 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.

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 Chief Executive Officer and Chief 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 and 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.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of 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). Our management concluded that our internal control over financial reporting was effective as of December 31, 2015.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

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	83	Chairman of the Board, Director
Roelof Rongen	50	Chief Executive Officer, Director
Jerome D. Jabbour	41	President
Raphael J. Mannino	68	Senior Vice President and Chief Technology Officer
Abdel A. Fawzy	65	Executive Vice President, Pharmaceutical Development and Supply Chain
Gary Gaglione	63	Vice President of Finance and Accounting and Acting Chief Financial Officer
Douglas F. Kling	42	Senior Vice President for Clinical Development and Project Management
Stefano Ferrari	55	Director
Adam Stern	51	Director
James S. Scibetta	51	Director

Management

Roelof Rongen has served as our Chief Executive Officer and one of our directors since July 2013 and as President, Chief Executive Officer a co-founder and a director of Matinas BioPharma since April 2012. He is also the Founder and Chairman of Essential Fatty Acid Therapeutics LLC, a biotech company focused on the development of innovative fatty acid derivatives. Prior to Matinas BioPharma, Mr. Rongen was Executive Vice President North American Operations for Trygg Pharma AS (subsequently named EPAX AS) (2009-2012) and Vice President of Life Cycle Management and Intellectual Property at Reliant Pharmaceuticals, Inc., or Reliant (2000-2008). While at Reliant, Mr. Rongen held various earlier positions, including head of the Omacor®/Lovaza® launch team, Executive Director of Marketing for Lescol® and Executive Director of Business Development. Prior to Reliant, Mr. Rongen was also Global Product Director for Humira® at BASF Pharma (1998-2000), later acquired by Abbott Laboratories; a consultant at The Wilkerson Group in New York (1995-1998) and Arthur D. Little in Amsterdam (1990-1993), and a Research Fellow in biochemistry at Baylor University in Texas (1989-1990). Mr. Rongen earned an MBA from Kellogg GSM at Northwestern University in Evanston, IL, and a graduate degree in Molecular Sciences from Wageningen University in the Netherlands.

Jerome D. Jabbour, JD became our President during 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 the July 2013 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 and US General Counsel of Wockhardt Limited (2008-2012) and Senior Counsel 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.

Raphael J. Mannino has served as our Senior Vice President and Chief Technology 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.

Abdel A. Fawzy, PhD has served as our Executive Vice President for Pharmaceutical and Supply Chain Development since July 2013 and as Executive Vice President for Pharmaceutical and Supply Chain Development of Matinas BioPharma since August 2011. Dr. Fawzy is a Co-Founder of Matinas BioPharma. Prior to Matinas BioPharma, Dr. Fawzy was a founder of expert consulting firm DeMelle BioPharma (2008-2012) and Executive Director Pharmaceutical Development at Reliant, from 2000 to 2008. Earlier in his career, Dr. Fawzy held pharmaceutical development positions at Ascent Pharmaceuticals, Inc. (1994-2000), DuPont (1990-1994) and Squibb Marsam Pharmaceuticals (1989-1990). He is the inventor on 15 published patents and patent applications all related to the health and pharmaceutical development and manufacturing processes. Dr. Fawzy received his Ph.D. in Pharmaceutical Technology from Tuebingen University in Germany, a Pharmacy degree from Temple University in Philadelphia, PA, and a MS in Pharmaceutical Technology from the Cairo School of Pharmacy in Egypt.

Gary Gaglione, CPA has served as our Acting Chief Financial Officer, Vice President of Finance & Accounting since April 2013. Prior to joining us as a full time employee, Mr. Gaglione was President of MCM Consulting LLC from 2011 until October 2013. Prior to MCM Consulting, Mr. Gaglione was Senior Director of Finance at Shionogi USA, Inc. (2011). In 2009 and 2010, he was Vice President of Finance and Controller for Phytomedics, Inc. Prior to Phytomedics, he was Controller for ProStrakan Inc.'s U.S. operations. From 2001 to 2008, Mr. Gaglione was an Executive Director at Reliant, initially as head of Planning, Budgets and Analysis, then, from 2006 on, as head of Internal Audit and Sarbanes Oxley Compliance in preparation for a potential Reliant initial public offering. Before Reliant, he held numerous finance positions of increasing responsibility at the U.S. subsidiary of Hoffmann-La Roche Inc. (1976-2001), including Vice President of R&D Finance (1997-2001).. He started his finance career at KPMG LLP (1974-1976). Mr. Gaglione earned a B.S. degree in Business Administration with a major in Accounting from Villanova University and an MBA in Finance from Seton Hall University.

Douglas F. Kling has served as our Senior Vice President for Clinical Development since March 12, 2015. Prior to Matinas, Mr. Kling held various positions at Omthera Pharmaceuticals, Inc. (acquired by AstraZeneca PLC in 2013) from August 2010 to December 2014, most recently as Senior Vice President of Clinical Development and Project Management. Prior to that, Mr. Kling served as Senior Director, Project Management at Shionogi USA Inc. (July 2009 to July 2010), as Senior Director, Program Management at The Medicines Company (April 2008 to July 2009) and in a variety of positions at Reliant (November 2000 to March 2008), most recently as Director, R&D Project Management. Mr. Kling earned his B.S. in biological sciences from Duke University and his M.B.A. from Rutgers Business School.

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.

Roelof Rongen. See description under "Management."

Stefano Ferrari has served on our board of directors since July 2013 and as a director of Matinas BioPharma since October 2012. Mr. Ferrari is the CEO and a director of Prime Acquisition Corp., a private equity fund focusing on real estate and renewable energy, a position he has held since October 2013. He is also the founder and managing member of Chestnut Hill Sciences, LLC (2004), a human and animal health care company dedicated to the development of dietary supplements, including omega-3 based products. He is the founder of Murami Pharma, Inc. ("Murami") and has served as its CEO since its inception in 2011. Murami is a biopharmaceutical development stage company focusing on small-peptide therapeutics. Prior to Murami, Mr. Ferrari was the CEO of Bioseutica B.V. (2008-2011), a multinational holding company comprising KD-Pharma, a leading manufacturer of omega-3-concentrates, and the leading lysozyme manufacturers Fordras and Neova Technologies, amongst others. Over the last 17 years, Mr. Ferrari was founder, common shareholder and senior executive of several multinational companies operating in the pharmaceutical, food and ingredients industries. Besides Bioseutica, these companies include Prospa B.V. (1995-2002), a multinational holding company in the pharmaceutical industry, Fordras S.A. (2002-2008), ProAparts Lda (2001-2012), and Societa Prodotti Antibiotici S.p.A., the Italian pharmaceutical company that developed and marketed polyene antifungal medications. Mr. Ferrari has served on several boards, including Ikonisys Inc., Carigent Therapeutics, Inc., The Richard B. Fisher Center for Performing Arts, and St. Simeon Lda, a private family fund. He has 25 years of experience in investing in diverse industries, including real estate, pharmaceuticals, and media and entertainment. Mr. Ferrari earned his B.A. degree in International Business Administration from the University of San Francisco. We believe Mr. Ferrari is qualified to serve on our board of directors due to his extensive expertise and experience in the development and marketing of polyene antifungal medications, his extensive contacts in the manufacturing industry related to omega-3 based products and also his M&A experience.

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.

James S. Scibetta has served as a member of our board of directors since November 2013. He is currently 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.

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.

Committees of the Board

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

Audit Committee . The Audit Committee oversees and monitors our financial reporting process and internal control system, review and evaluate the audit performed by our registered independent public accountants and report 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. The Board adopted a written charter for the Audit Committee, which is available on our website. James Scibetta, Herbert Conrad and Stefano Ferrari serve as members of the Audit Committee with James Scibetta, serving as its chairman. All of the members of the Audit Committee have been determined to be financially literate and are considered independent directors as defined under The NYSE MKT'S listing standards and applicable SEC rules and regulations. Mr. Scibetta qualifies as an audit committee "financial expert" as that term is defined by Commission regulations.

Compensation Committee . The Compensation Committee provides advice and make recommendations to the Board in the areas of employee salaries, benefit programs and director compensation. The Compensation Committee also reviews the compensation of our President and Chief Executive Officer and makes recommendations in that regard to the Board as a whole. The Board adopted a written charter for the Compensation Committee, which is available on our website. Stefano Ferrari, Herbert Conrad, and James Scibetta serve as members of the Compensation Committee, with Stefano Ferrari serving as its chairman. All of the members of the Compensation Committee are considered independent directors as defined under The NYSE MKT's listing standards.

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. The Board adopted a written charter for the Nominating and Corporate Governance Committee, which is available on our website. Herbert Conrad, Stefano Ferrari and James Scibetta serve as members of the Nominating and Corporate Governance Committee, with Herbert Conrad serving as its chairman. All of the members of the Nominating and Corporate Governance Committee are considered independent directors as defined under The NYSE MKT's listing standards.

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

Since our common stock is not registered under Section 12 of the Exchange Act, our directors and executive officers and persons who beneficially own more than 10% of our common stock are not required to file with the SEC various reports as to their ownership of and activities relating to our common stock.

Item 11. Executive Compensation

Summary Compensation Table – 2015

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, 2015 for services rendered in all capacities to us for the years ended December 31, 2015 and December 31, 2014. These individuals are our named executive officers for 2015.

Name and Principal Position [(1)]	Year	Salary ($)	Bonus ($)	Option Awards(1) ($)	All Other Compensation($)	Total ($)
Roelof Rongen	2015	300,000	132,000	101,638	-	533,638
Chief Executive Officer	2014	300,000	50,000	268,813		618,813
Abdel A. Fawzy	2015	250,000	60,000	33,879	-	343,879
Executive Vice President, Supply Chain Development	2014	250,000	25,000	268,813	-	543,813
Jerome D. Jabbour, *President*	2015	293,000	90,750	59,289	-	443,039
	2014	275,000	30,000	268,813	-	573,813

(1) Amounts reflect the grant date fair value of option awards granted in 2015 and 2014 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.

Narrative Disclosure to Summary Compensation Table

Employment Agreements with Our Named Executive Officers

On July 30, 2013 we entered into an employment agreement with Mr. Rongen for a period of three years. Under the terms of Mr. Rongen's employment agreement, he received a signing bonus of $150,000 and will receive a base salary of $300,000 per year. In addition, Mr. Rongen will also be eligible to receive an annual bonus, which is targeted at 40% 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. Rongen may also be eligible to receive option grants at the discretion of our Compensation Committee. In October 2013, Mr. Rongen received a grant of 350,000 options at an exercise price of $0.94 per share. The options vest in equal monthly installments over three years from August 1, 2013. If we terminate Mr. Rongen's employment without cause or Mr. Rongen resigns with good reason, we are required to pay him a 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. If we terminate Mr. Rongen's employment without cause during the 24 month period immediately following a change of control or Mr. Rongen resigns with good reason during the 24 month period immediately following a change of control, we are required to pay him a 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. Rongen's employment agreement provides for an increase in base salary of $50,000 annually, upon a future closing of an additional round of financing of at least $15 million and the initiation of the first Phase III study of MAT9001. Mr. Rongen will also be subject to a customary non-disclosure agreement, pursuant to which Mr. Rongen 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. As part of our cost reduction measures, we have entered into a letter agreement with Mr. Rongen effective as of April 1, 2016 that provides for, among other things, a 10% reduction in base salary through December 31, 2016 and a requirement that the executive contribute 20% of the applicable premium cost for healthcare coverage under the Company's group health plan. The letter agreement also provides that for purposes of calculating any severance payments, the base salary will be the base salary prior to such temporary reduction and therefore the temporary reduction in base salary will not impact the amounts that would be paid to the executive if his employment was terminated.

On July 30, 2013 we entered into an employment agreement with Dr. Fawzy for a period of three years. Under the terms of Dr. Fawzy's employment agreement, he received a signing bonus of $125,000 and he will receive a base salary of $250,000 per year. In addition, Dr. Fawzy will also be 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. Dr. Fawzy will also be eligible to receive option grants at the discretion of our Compensation Committee. In October 2013, Dr. Fawzy received a grant of 350,000 options at an exercise price of $0.94 per share. The options vest in equal monthly installments over three years from August 1, 2013. If we terminate Dr. Fawzy's employment without cause or Dr. Fawzy resigns with good reason, we are required to pay him a 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 Dr. Fawzy's employment without cause during the 24 month period immediately following a change of control or Dr. Fawzy resigns with good reason during the 24 month period immediately following a change of control, we are required to pay him a 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. Dr. Fawzy's employment agreement provides for an increase in base salary of $50,000 annually, upon a future closing of an additional round of financing of at least $15 million and the initiation of the first Phase III study of MAT9001. Dr. Fawzy will also be subject to a customary non-disclosure agreement, pursuant to which Dr. Fawzy 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. As part of our cost reduction measures, we have entered into a letter agreement with Dr. Fawzy effective as of April 1, 2016 that provides for, among other things, a 10% reduction in base salary through December 31, 2016 and a requirement that the executive contribute 20% of the applicable premium cost for healthcare coverage under the Company's group health plan. The letter agreement also provides that for purposes of calculating any severance payments, the base salary will be the base salary prior to such temporary reduction and therefore the temporary reduction in base salary will not impact the amounts that would be paid to the executive if his employment was terminated.

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 will receive a base salary of $275,000 per year. In addition, Mr. Jabbour will also be 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 will also be eligible to receive option grants at the discretion of our Compensation Committee. On October 4, 2013, Mr. Jabbour received a grant of 200,000 options at an exercise of $0.94 per share. The options will vest in equal monthly installments over three years from the date of grant. Mr. Jabbour also received a grant of 150,000 at an exercise price of $0.94 per share, which vests in equal monthly installments over three years beginning on August 1, 2013. If we terminate Mr. Jabbour's employment without cause or Mr. Jabbour resigns with good reason, we are required to pay him a 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 a 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 will also be 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. As part of our cost reduction measures, we have entered into a letter agreement with Mr. Jabbour effective as of April 1, 2016 that provides for, among other things, a 10% reduction in base salary through December 31, 2016 and a requirement that the executive contribute 20% of the applicable premium cost for healthcare coverage under the Company's group health plan. The letter agreement also provides that for purposes of calculating any severance payments, the base salary will be the base salary prior to such temporary reduction and therefore the temporary reduction in base salary will not impact the amounts that would be paid to the executive if his employment was terminated.

Outstanding Equity Awards at Fiscal Year-End Table – 2015

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, 2015.

	Option Awards			
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date
Roelof Rongen	100,008	199,992	$ 0.41	Jan. 27,2025
	262,521	87,479	$ 1.28	July 20, 2024
	281,967	68,033	$ 0.94	October 2,2023
Abdel A. Fawzy	33,336	66,664	$ 0.41	Jan. 27, 2025
	262,521	87,479	$ 1.28	July 20, 2024
	281,967	68,056	$ 0.94	October 2,2023
Jerome D. Jabbour	58,338	116,662	$ 0.41	Jan. 27, 2025
	262,521	87,479	$ 1.28	July 20, 2024
	270,855	79,145	$ 0.94	October 3, 2023

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 . The current aggregate number of shares of common stock available for issuance in connection with awards granted under the 2013 Plan is 9,541,706 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.

Section 162(m) Compliance . If stock or cash-based awards are intended to satisfy the conditions for deductibility under Section 162(m) of the Code as "performance-based compensation," the performance criteria will be selected from among the following, which may be applied to our Company as a whole, any subsidiary or any division or operating unit thereof: (a) pre-tax income; (b) after-tax income; (c) net income; (d) operating income or profit; (e) cash flow, free cash flow, cash flow return on investment, net cash provided by operations, or cash flow in excess of cost of capital; (f) earnings per share; (g) return on equity; (h) return on sales or revenues; (i) return on invested capital or assets; (j) cash, funds or earnings available for distribution; (k) appreciation in the fair market value of the common stock; (l) operating expenses; (m) implementation or completion of critical projects or processes; (n) return on investment; (o) total return to stockholders; (p) dividends paid; (q) net earnings growth; (r) related return ratios; (s) increase in revenues; (t) the Company's published ranking against its peer group of pharmaceutical companies based on total stockholder return; (u) net earnings; (v) changes (or the absence of changes) in the per share or aggregate market price of the common stock; (w) number of securities sold; (x) earnings before or after any one or more of the following items: interest, taxes, depreciation or amortization, as reflected in the Company's financial reports for the applicable period; (y) total revenue growth; (z) economic value created; (aa) operating margin or profit margin; (bb) share price or total shareholder return; (cc) cost targets, reductions and savings, productivity and efficiencies; (dd) strategic business criteria, consisting of one or more objectives based on meeting objectively determinable criteria: specified market penetration, geographic business expansion, progress with research and development activities, investor satisfaction, employee satisfaction, human resources management, supervision of litigation, information technology, and goals relating to acquisitions, divestitures, joint ventures and similar transactions, and budget comparisons; (ee) objectively determinable personal or professional objectives, including any of the following performance goals: the implementation of policies and plans, the negotiation of transactions, the development of long term business goals, formation of joint ventures, research or development collaborations, and the completion of other corporate transactions, and (ff) any combination of, or a specified increase or improvement in, any of the foregoing.

At the end of the performance period established in connection with any award, the Compensation Committee will determine the extent to which the performance goal or goals established for such award have been attained, and shall determine, on that basis, the number of performance shares or performance units included in such award that have been earned and as to which payment will be made. The Compensation Committee will certify in writing the extent to which it has determined that the performance goal or goals established by it for such award have been attained.

With respect to awards intended to be performance-based compensation under Section 162(m) of the Code, no participant of the 2013 Plan may receive in any one fiscal year (a) options or stock appreciation rights relating to more than 2,500,000 shares of our common stock, and (b) stock units, restricted shares, performance shares, performance units or other stock-based awards that are denominated in shares of common stock relating to more than 2,500,000 shares of our common stock in the aggregate. The maximum dollar value payable to any participant for a fiscal year of the Company with respect to any awards under the 2013 Plan payable in cash is $2,500,000.

***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.

Director Compensation Table – 2015

The following table summarizes the annual compensation for our non-employee directors during 2015.

Name	Stock Awards($) (1)	Option Awards ($) (1)	Total ($)
Herbert Conrad	72,500	16,940	88,940
Stefano Ferrari	45,000	16,940	61,940
James S. Scibetta	50,000	16,940	66,940
Adam Stern	35,000	16,940	51,940

(1) Amounts reflect the grant date fair value of stock awards and option awards granted in 2015 in accordance with Accounting Standards Codification Topic 718. These amounts do not correspond to the actual value that will be recognized by the directors.

On March 7, 2016, non-employee directors were awarded stock awards as compensation for 2016 in the same dollar amount as 2015 (see table above). These stock awards vest on a quarterly basis based on service during 2016.

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 7, 2016 by:

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

Beneficial ownership is determined based on the rules and regulations of the Commission. 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 57,593,414 shares outstanding as of March 7, 2016. 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 7, 2016. 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)	10,721,760	18.6%
Laurence G. Allen(2)	4,511,250	7.9%
Directors and Executive Officers		
Roelof Rongen(3)	4,321,285	7.5%
Herbert Conrad(4)	4,244,504	7.4%
Stefano Ferrari(5)	1,158,314	2.0%
James Scibetta (6)	702,651	1.2%
Adam Stern (7)	7,826,323	13.6%
Abdel A. Fawzy, Ph.D.(8)	2,395,240	4.2%
Gary Gaglione(9)	227,793	*
Jerome Jabbour(10)	1,477,487	2.6%
Douglas King(11)	232,790	*
Raphael Mannino (12)	1,592,418	2.8%
Directors and Executive Officers as a group (10 persons) (13)	24,178,805	42.0%

* Less than 1%

(1) Includes (i) 75,000 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and (ii) 5,681,880 shares of common stock and 4,806,880 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and are owned by GJG Life Sciences LLC, which is beneficially-owned by Ms. Lorenzo.

(2) Includes (i) 100,000 shares of common stock and 50,000 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and registered in the name of Mr. Allen's individual retirement account, (ii) 50,000 shares of common stock and 25,000 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and are owned by ACP Partners, LP, which is beneficially-owned by Mr. Allen, (iii) 2,000,000 shares of common stock and 1,500,000 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and are owned by ACP X, LP, which is beneficially-owned by Mr. Allen. (iv) 86,250 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and are owned by NYPPEX, LLC, which is beneficially owned by Mr. Allen, and (v) 400,000 shares of common stock and 300,000 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and are owned by LGA Investments Family Limited Partnership, which is beneficially owned by Mr. Allen.

(3) Includes (i) 50,000 shares of common stock issuable upon exercise of outstanding Warrants that ate exercisable within sixty days of March 7, 2016 and (ii) includes 786,869 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 7, 2016. Does not include 588,132 shares of common stock underlying options that are not exercisable within sixty days of March 7, 2016

(4) Includes (i) 1,875,000 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and (ii) 484,483 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 7, 2016. Does not include 125,518 shares of common stock underlying options that are not exercisable within sixty days of March 7, 2016.

(5) Includes (i) 351,563 shares of common stock and 250,000 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and are owned by 1010 Holdings LLC, which is beneficially owned by Mr. Ferrari and (ii) 378,710 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 7, 2016. Does not include 103,790 shares of common stock underlying options that are not exercisable within sixty days of March 7, 2016.

(6) Includes (i) 100,000 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and (ii) includes 307,038 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 7, 2016. Does not include 115,462 shares of common stock underlying options that are not exercisable within sixty days of March 7, 2016.

(7) Includes (i) 4,419,168 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016, (ii) 323,706 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 7, 2016, (iii) 200,000 shares of common stock and 100,000 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and are owned by Pavilion Capital Partners, LLC, which is wholly-owned by Mr. Stern, (iv) 200,000 shares of common stock and 100,000 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and are owned by Piper Ventures Partners, LLC, which is wholly-owned by Mr. Stern, (v) 250,000 shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and are owned by SternAegis Advisers LLC, which is wholly-owned by Mr. Stern, (vi) 1,000,000 shares held by AKS Family Foundation and (vii) 600,000 shares of common stock held by AKS Family Partners. Does not include 98,794 shares of common stock underlying options that are not exercisable within sixty days of March 7, 2016.

(8) Includes 675,054 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 7, 2016. Does not include 224,946 shares of common stock underlying options that are not exercisable within sixty days of March 7, 2016.

(9) Includes (i) 20,000 Shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and (ii) includes 187,793 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 7, 2016. Does not include 92,207 shares of common stock underlying options that are not exercisable within sixty days of March 7, 2016.

(10) Includes 718,113 shares of common stock issuable upon exercise of options that are exercisable within 60 days of March 7, 2016. Does not include 506,887 shares of common stock underlying options that are not exercisable within sixty days of March 7, 2016.

(11) Includes (i) 40,000 Shares of common stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 7, 2016 and (ii) includes 152,790 shares of common stock issuable upon exercise of options that are exercisable within sixty days of March 7, 2016. Does not include 397,210 shares of common stock underlying options that are not exercisable within sixty days of March 7, 2016.

(12) Includes 172,853 shares of common stock issuable upon exercise of options that are exercisable within 60 days of March 7, 2016. Does not include 237,147 shares of common stock underlying options that are not exercisable within sixty days of March 7, 2016.

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

Equity Compensation Plan Information

The following table provides information with respect to our compensation plans under which equity compensation was authorized as of December 31, 2015.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column a) (c) [2]
Equity compensation plans approved by security holders [1]	7,474,434	$ 0.93	2,067,272
Equity compensation plans not approved by security holders	500,000	$ 0.94	—
Total	7,974,434	$ 0.93	2,067,272

(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 2,287,206 shares were automatically made available for issuance on the first trading day of 2016, which represents 4% of the number of shares outstanding on December 31, 2015; these shares are excluded from this calculation.

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

Certain Relationships and Related Party Transactions

Other than compensation arrangements for our named executive officers and directors, we describe below each transaction or series of similar transactions, since January 1, 2013, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $100,000; 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.

Formation of Matinas

In connection with our formation in June 2013, we sold an aggregate of 7,500,000 shares of our common stock and 3,750,000 warrants (the "Formation Warrants") to purchase 3,750,000 shares of our common stock, at an exercise price of $2.00 per share, for an aggregate of $375,000 (at a purchase price of $0.10 for two shares and one warrant), including 2,000,000 shares and warrants to purchase 1,000,000 shares of our common stock to Adam Stern and entities owned by Mr. Stern. Mr. Stern is a member of our board of directors. In addition, at such time, we sold to an entity owned by Mr. Stern Formation Warrants to purchase 250,000 shares of our common stock at a purchase price of $10,000 (a price of $0.04 per warrant).

2013 Private Placement

In July and August 2013, we completed a private placement, the 2013 Private Placement, under which we sold an aggregate of 15,000,000 shares of our common stock and warrants to purchase an aggregate of 7,500,000 shares of our common stock with an exercise price of $2.00 per share, which warrants are exercisable for a period of five years from the initial closing date of July 30, 2013 (the "2013 Investor Warrants"). In the 2013 Private Placement, Herbert Conrad, our chairman of the board, purchased 250,000 shares of common stock and 2013 Investor Warrants to purchase 125,000 shares of our common stock. Aegis Capital Corp., or Aegis, acted as the placement agent, or Placement Agent, for the 2013 Private Placement. The gross proceeds to us from the 2013 Private Placement were $15 million.

In connection with the 2013 Private Placement, we paid the Placement Agent (i) a cash fee of $1,500,000 and (ii) a non-accountable expense allowance equal to $450,000. Mr. Stern is an affiliate of Aegis. In addition, as part of its compensation for acting as placement agent for the 2013 Private Placement, we issued (x) warrants to the Placement Agent to purchase 750,000 shares of our common stock with an exercise price of $2.00 per share and (y) warrants to the Placement Agent to purchase 1,500,000 shares of our common stock with an exercise price of $1.00 per share. Such warrants, the 2013 Placement Agent Warrants, contain a "cashless exercise" feature and are exercisable at any time prior to July 30, 2018.

In connection with the closing of the 2013 Private Placement, the Placement Agent was granted the right to appoint one member of our Board of Directors for a two-year term from the initial closing. Adam Stern, the Aegis Nominee, was appointed to the Board of Directors at the initial closing and his successor, if any, will be chosen by the Placement Agent, subject to the reasonable approval of the Company and the Voting Agreement described below.

We have agreed to engage the Placement Agent as our warrant solicitation agent in the event the 2013 Investor Warrants are called for redemption and shall pay a warrant solicitation fee to the Placement Agent equal to five (5%) percent of the amount of funds solicited by the Placement Agent upon the exercise of the 2013 Investor Warrants following such call for redemption.

Consulting Agreement

We also entered into a consulting agreement with the Placement Agent in July 2013. The consulting agreement had a term of 12 months pursuant to which we paid the Placement Agent $20,000 per month. Under the terms of the consulting agreement, the Placement Agent agreed to provide customary financial advisory services as reasonably requested by us, including consulting services for financing and capital markets activity, mergers, acquisitions, joint ventures and licensing agreements. This consulting agreement terminated on July 30, 2014.

2015 Private Placement

In March and April 2015, we completed a private placement, or the 2015 Private Placement, pursuant to which we sold to accredited investors an aggregate of 20,000,000 units at a price of $0.50 per unit, with each unit consisting of: (i) one share of our common stock, and (ii) a five-year warrant to purchase one share of common stock at an exercise price of $0.75 per share (the "2015 Investor Warrants"). The gross proceeds to us from the 2015 Private Placement were $10.0 million. Certain of our officers, directors and holders of more than 5% of our capital stock purchased units in the 2015 Private Placement as set forth below.

Name	Number of Units Purchased	Aggregate Purchase Price Paid
GJG Life Sciences, LLC	3,935,880	$ 1,967,940
Laurence G. Allen and affiliated entities	1,200,000	600,000
Herbert Conrad	1,000,000	500,000
Adam Stern and affiliated entities	800,000	400,000
James Scibetta	100,000	50,000
Roelof Rongen	50,000	25,000
Douglas Kling	40,000	20,000
Gary Gaglione	20,000	10,000

We entered into a Placement Agency Agreement with Aegis Capital Corp. pursuant to which Aegis acted as our exclusive placement agent for the 2015 Private Placement. Immediately prior to the 2015 Private Placement, the Placement Agent and its affiliates beneficially owned an aggregate of more than 10% of our outstanding equity securities. In addition, Adam Stern, Head of Private Equity Banking at Aegis, is a member of our board of directors. Pursuant to the terms of the Placement Agency Agreement, in connection with the 2015 Private Placement, we paid the Placement Agent an aggregate cash fee of $1,000,000 and non-accountable expense allowance of $300,000 and have issued to the Placement Agent warrants (substantially similar to the 2015 Investor Warrants) to purchase 2,000,000 shares of common stock at $0.50 per share and additional warrants to purchase 2,000,000 shares of common stock at $0.75 per share. In addition, we agreed to engage the Placement Agent as our warrant solicitation agent in the event the 2015 Investor Warrants are called for redemption and shall pay a warrant solicitation fee to the Placement Agent equal to five (5%) percent of the amount of funds solicited by the Placement Agent upon the exercise of the 2015 Investor Warrants following such redemption.

Voting Agreement

In connection with the initial closing of the 2013 Private Placement, the stockholders of Matinas BioPharma, Inc. ("Matinas BioPharma") prior to the 2013 Merger (as defined below) and the 2013 Private Placement (the "Matinas Stockholders") and the stockholders of the Company prior to the Merger (the "Company Stockholders"), entered into a Voting Agreement (the "Voting Agreement"). Pursuant to the terms of the Voting Agreement, (i) the Matinas Stockholders have the right to nominate four (4) members to our Board (the "Matinas Stockholders' Nominees"), (ii) the Company Stockholders will vote in favor of the election and removal of the Matinas Stockholders' Nominees and (iii) the Company Stockholders shall nominate the Aegis Nominee to our Board and (iv) the Matinas Stockholders shall vote in favor of the election and removal of the Aegis Nominee. The Voting Agreement will expire upon the earlier of (i) the approval of at least 75% of the Matinas Stockholders and the Company Stockholders voting together based upon their ownership of our common stock or (ii) the closing of a firm commitment underwritten public offering of shares of our common stock resulting in gross proceeds of at least $20 million.

2013 Merger Transaction

In July 2013, Matinas BioPharma, Inc. entered into entered into a merger agreement (the "2013 Merger Agreement") with Matinas Merger Sub, Inc., a Delaware corporation and our wholly owned subsidiary, or Merger Sub. Pursuant to the terms of the 2013 Merger Agreement, as a condition of and contemporaneously with the initial closing of the 2013 Private Placement, Merger Sub merged (the "2013 Merger") with and into Matinas BioPharma and Matinas BioPharma became a wholly owned subsidiary of ours. In connection with the 2013 Merger, all shares of common stock and preferred stock of Matinas BioPharma were cancelled and the stockholders of Matinas BioPharma received an aggregate of 9,000,000 shares of our common stock and warrants to purchase 1,000,000 shares of our common stock at an exercise price of $2.00 per share (the "Merger Warrants"), including Herbert Conrad, our chairman of the board, who received 351,563 shares of our common stock and 250,000 Merger Warrants; Roelof Rongen, our president and chief executive officer, who received 3,417,186 shares of our common stock, Abdel A. Fawzy, our executive vice president, pharmaceutical development and supply chain development, who received 1,708,593 shares of our common stock; George Bobotas, our executive vice president and chief scientific officer, and his spouse, who received an aggregate of 1,366,875 shares of our common stock; Jerome Jabbour, our executive vice president, chief business officer and general counsel, who received 759,374 shares of our common stock; and Stefano Ferrari, a member of our board of directors, through an entity controlled by him, who received 351,563 shares of our common stock and 250,000 Merger Warrants.

Warrant Private Placement

Contemporaneously with the initial closing of the 2013 Private Placement, we sold 500,000 warrants ("Private Placement Warrants") in a private placement to Herbert Conrad, our chairman of the board, for a purchase price of $0.04 per warrant. The Private Placement Warrants have an exercise price of $2.00 per share. The Private Placement Warrants were offered to all preferred stockholders of Matinas BioPharma prior to the 2013 Merger, including Mr. Conrad.

Vendor Agreement

Since January 1, 2011, we have submitted orders for the purchase of an omega-3 fatty acid concentrate from KD-Pharma Bexbach GmbH, or KD Pharma. For the years ended December 31, 2013, December 31, 2014 and December 31, 2015, these orders totaled $ 22 thousand, $ 258 thousand and $ 46 thousand, respectively. Mr. Ferrari, a member of our board, is the brother of a part owner of the holding company that owns KD Pharma.

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, nonappealable 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, Stefano Ferrari and James Scibetta sare "independent directors" as such term is defined in the rules of The NYSE MKT'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, 2015 and December 31, 2014, by EisnerAmper LLP, the Company's independent registered public accounting firm.

	Year Ended December 31,	
	2015	2014
	(in thousands)	
Audit Fees	$ 100	$ 123
Tax Fees	9	4
Total Fees	$ 109	$ 127

Audit Fees consist of fees for professional services and expenses relating to the audit of our annual financial statements, the audit of our internal control over financial reporting 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).

4.1	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).
4.2	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).
4.3	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).
4.4	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.)
4.5	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.)
4.6	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.)
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). †
10.9	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). †
10.10	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). †
10.11	Employment Agreement effective as of October 4, 2013 between the Company and Jerome 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). †

10.12	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). †
10.13	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). †
10.14	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).
10.15	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.) +.
10.16	Employment Agreement, dated March 12, 2015, between Matinas BioPharma Holdings, Inc. and Douglas F. Kling. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on March 19, 2015). †
10.17	Placement Agency Agreement dated March 19, 2015 between the Company and Aegis Capital Corp. (incorporated herein by reference to Exhibit 10.20 of the Company's Registration Statement on Form S-1 (Reg. No. 333-193455), filed with the SEC on April 17, 2015).
10.18	Form of Subscription Agreement for the Company's 2015 private placement. (incorporated herein by reference to Exhibit 10.21 of the Company's Registration Statement on Form S-1 (Reg. No. 333-193455), filed with the SEC on April 17, 2015).
10.19	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).
10.20	Separation and Consulting Agreement between George Bobotas and Matinas BioPharma Holdings, Inc., dated September 29, 2015. (incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on October 1, 2015).
21.1	Subsidiaries Index*
23.1	Consent of Eisner Amper 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, 2015, formatted in XBRL (eXtensible Business Reporting Language), is filed electronically herewith: (i) Consolidated Balance Sheets as of December 31, 2015 and 2014; (ii) Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2015 and 2014; (iii) Consolidated Statement of Changes in Stockholders' Equity (Deficit) for the Years Ended December 31, 2015 and 2014; (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2015 and 2014; 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.

SIGNATURES

Pursuant to the requirements of the Securities Act, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Bedminster, State of New Jersey on March 30, 2016.

MATINAS BIOPHARMA HOLDINGS, INC.

By: /s/ Roelof Rongen
Name: Roelof Rongen
Title: Chief Executive Officer

By: /s/ Gary Gaglione
Name: Gary Gaglione
Title: Acting 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/ Roelof Rongen Roelof Rongen	Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2016
/s/ Gary Gaglione Gary Gaglione	Acting Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2016
/s/ Herbert Conrad Herbert Conrad	Chairman of the Board	March 30, 2016
/s/ Stefano Ferrari Stefano Ferrari	Director	March 30, 2016
/s/ James S. Scibetta James S. Scibetta	Director	March 30, 2016
/s/ Adam K. Stern Adam K. Stern	Director	March 30, 2016

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Matinas BioPharma Holdings, Inc.

We have audited the accompanying consolidated balance sheets of Matinas BioPharma Holdings, Inc. and Subsidiaries (the "Company") as of December 31, 2015 2014, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2015. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Matinas BioPharma Holdings, Inc. and Subsidiaries as of December 31, 2015 and 2014, and the consolidated results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note B to the consolidated financial statements, the Company has limited liquidity and experienced significant losses and negative cash flows from operations since inception, and these factors have raised substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note B. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ EisnerAmper LLP

Iselin, New Jersey
March 30, 2016

Matinas BioPharma Holdings Inc.
Condensed Consolidated Balance Sheets

	December 31, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS		
Cash	**$ 3,226,997**	**$ 2,590,713**
Restricted cash - current	**100,326**	**100,000**
Prepaid expenses	**231,797**	**114,425**
Total current assets	**3,559,120**	**2,805,138**
Equipment - net	**377,723**	**339,995**
In-process research and development	**3,017,377**	**-**
Goodwill	**1,336,488**	**-**
Other assets including long term security deposit	**115,370**	**216,317**
TOTAL ASSETS	**$ 8,406,078**	**$ 3,361,450**
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	**$ 497,842**	**$ 271,155**
Accrued expenses	**610,206**	**802,746**
Deferred rent liability	**9,225**	**-**
Lease liability	**11,261**	**44,362**
Total current liabilities	**1,128,534**	**1,118,263**
LONG TERM LIABILITIES		
Deferred tax liability	**1,205,141**	**-**
Lease liability - long term	**-**	**15,291**
TOTAL LIABILITIES	**2,333,675**	**1,133,554**
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Common stock par value $ 0.0001, 250,000,000 and 150,000,000 shares authorized, at December 31, 2015 and 2014, respectively; 57,180,148 issued and outstanding as of December 31, 2015; 32,292,650 issued and outstanding as of December 31, 2014	**5,719**	**3,230**
Additional paid in capital	**29,253,848**	**16,276,430**
Accumulated deficit	**(23,187,164)**	**(14,051,764)**
Total stockholders' equity	**6,072,403**	**2,227,896**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 8,406,078**	**$ 3,361,450**

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

Matinas BioPharma Holdings, Inc.
Condensed Consolidated Statements of Operations

	For the Year Ended December 31,	
	2015	**2014**
Revenue:		
Contract research revenue	$ 194,494	$ -
Costs and Expenses:		
Research and development	5,292,193	5,175,520
General and administrative	4,813,800	5,289,479
Total costs and expenses	10,105,993	10,464,999
Loss from operations	(9,911,499)	(10,464,999)
Sale of New Jersey net operating loss	756,472	269,127
Other income/(expense), net	19,627	(25,173)
Net loss	$ (9,135,400)	$ (10,221,045)
Net loss per share - basic and diluted	$ (0.18)	$ (0.32)
Weighted average common shares outstanding:		
Basic and diluted	51,481,002	32,076,717

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

MATINAS BIOPHARMA HOLDINGS, INC.
STATEMENT OF STOCKHOLDERS' EQUITY
December 31, 2015

	Common Stock		Additional	Accumulated	Total Stockholders'
	(Shares)	(Amount)	Paid - in Capital	Deficit	Equity
Balance at December 31, 2013	**32,000,000**	**$ 3,200**	**$ 14,302,307**	**$ (3,830,719)**	**$ 10,474,788**
Stock Based Compensation	**-**	**-**	**1,821,402**	**-**	**1,821,402**
Issuance of common stock for serivces	**292,650**	**30**	**152,721**	**-**	**152,751**
Net loss for the year ended December 31, 2014	**-**	**-**	**-**	**(10,221,045)**	**(10,221,045)**
Balance at December 31, 2014	**32,292,650**	**3,230**	**16,276,430**	**(14,051,764)**	**2,227,896**
Shares issued for Aquarius Inc. Purchase January 29, 2015	**4,608,020**	**460**	**2,119,229**	**-**	**2,119,689**
Aquarius Inc. Contingent Equity Consideration	**-**	**-**	**753,346**	**-**	**753,346**
Private Placements	**20,000,000**	**2,001**	**8,520,163**	**-**	**8,522,164**
Private Placement Issuance Costs	**-**	**-**	**(7,945)**	**-**	**(7,945)**
Stock Based Compensation	**-**	**-**	**1,354,373**	**-**	**1,354,373**
Issuance of common stock as Compensation for services	**278,784**	**28**	**237,967**	**-**	**237,995**
Issuance of common stock for excercised options	**694**	**-**	**285**	**-**	**285**
Net Loss for the year ended December 31, 2015	**-**	**-**	**-**	**(9,135,400)**	**(9,135,400)**
Balance as of December 31, 2015	**57,180,148**	**$ 5,719**	**$ 29,253,848**	**$ (23,187,164)**	**$ 6,072,403**

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

Matinas BioPharma Holdings Inc.
Condensed Consolidated Statements of Cash Flow

	Year Ended December 31,	
	2015	**2014**
Cash flows from operating activities:		
Net loss	$ (9,135,400)	$ (10,221,045)
Adjustments to reconcile net loss to net cash (used in) operating activities:		
Depreciation and amortization	43,502	41,581
Deferred rent	9,225	-
Share based compensation and other expense	1,592,367	1,974,153
Changes in operating assets and liabilities, net of amounts acquired:		
Grant receivable	45,643	-
Prepaid expenses	(111,588)	(29,932)
Other assets	100,621	(539)
Accounts payable	(73,726)	(125,613)
Accrued expenses	(285,047)	400,199
Net cash used in operating activities	(7,814,403)	(7,961,196)
Cash flows from investing activities		
Equipment purchases	(76,179)	(288,519)
Acquisition of Aquarius - cash acquired	70,754	-
Net cash used in investing activities	(5,425)	(288,519)
Cash flows from financing activities:		
Issuance of common stock, net of offering expense	8,514,504	-
Payments of - lease liability	(48,392)	-
Payment of - notes payable	(10,000)	-
Net cash provided by financing activities	8,456,112	-
Net increase (decrease) in cash and cash equivalents	636,284	(8,249,715)
Cash and cash equivalents at beginning of period	2,590,713	10,840,428
Cash and cash equivalents at end of period	$ 3,226,997	$ 2,590,713
Supplemental non-cash financing activities		
Capital lease for equipment purchase	$ -	$ 111,095
Contingent equity consideration for Aquarius merger	$ 753,346	$ -
Stock consideration for Aquarius merger	$ 2,119,689	$ -

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

NOTE A – Nature of Business

[1] Corporate History

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

On July 11, 2013, and contemporaneously with the initial closing of a private placement in July and August 2013 described below, BioPharma entered into a merger agreement whereby it became a wholly owned subsidiary of Holdings (the "Merger") to effect its recapitalization plan. In connection with the Merger, the stockholders of BioPharma became the stockholders of the Holdings and received an aggregate of 9,000,000 shares of Holdings common stock and warrants to purchase 1,000,000 shares of Holdings common stock. For financial reporting purposes the accounting acquirer is BioPharma and accordingly, the historical financial statements of BioPharma are the continuing financial statements of the combined entity. In July and August of 2013, the Company completed a private placement of common stock (the "2013 Private Placement"), under which the Company sold an aggregate of 15,000,000 shares of common stock and warrants to purchase an aggregate of 7,500,000 shares of common stock . On February 12, 2014, the Company's S-1 covering the resale of certain shares of our common stock was declared effective by the Securities and Exchange Commission (the "SEC").

On January 29, 2015, we completed the acquisition of Aquarius (Aquarius Merger), a New Jersey-based, early-stage pharmaceutical company focused on the development of differentiated and orally delivered therapeutics based on a proprietary, lipid-based, drug delivery platform called "cochleate delivery technology." Following the Aquarius Merger, we are a clinical-stage biopharmaceutical company focused on identifying and developing safe and effective broad spectrum antifungal and anti-bacterial therapeutics for the treatment of serious and life-threatening infections, using our innovative lipid-crystal nano-encapsulation drug delivery platform. See Note D for additional information on this transaction.

On April 10, 2015, we completed a private placement ("2015 Private Placement"), under which the Company sold an aggregate of 20,000,000 shares of common stock and warrants to purchase 20,000,000 shares of common stock (see Note E for additional details) resulting in net proceeds of approximately $ 8.5 million after offering expenses.

[2] Proprietary Products and Technology Portfolios

Our proprietary cochleate lipid-crystal nano-particle delivery technology platform, licensed from Rutgers University on an exclusive worldwide basis, is designed specifically for the targeted and safe delivery of orally bioavailable pharmaceuticals directly to the site of infection or inflammation. This license comprises a range of issued patents and patent applications, as well as the use of proprietary know-how with respect to the manufacturing and testing of products using this technology.

Our lead product candidate using the cochleate delivery technology is MAT2203, an oral formulation of the broad spectrum intravenous(IV)-delivered anti-fungal agent amphotericin B. MAT2203 is under development for serious fungal infections and a single-escalating-dose Phase 1 study with MAT2203 has been completed. The Company is developing MAT2203 in collaboration with the National Institute of Allergy and Infectious Diseases, or NIAID, of the National Institutes of Health, or NIH. The U.S. Food and Drug Administration (FDA) has designated MAT2203 as a Qualified Infectious Disease Product (QIDP) with Fast Track status for the treatment of aspergillus. We are developing a pipeline of targeted delivery formulations by applying our cochleate oral delivery technology to a potentially broad array of proven medications, including MAT2501. MAT2501 is an oral cochleate formulation of the broad spectrum intravenous (IV)-delivered aminoglycoside antibiotic called amikacin, which is most often used for treating severe, hospital-acquired infections, including Gram-negative bacterial infections. The Company has an open Investigational New Drug (IND) application for MAT2501. MAT2501, has been granted a QIDP designation and Orphan Drug designation by the U.S. FDA.

In addition, the Company is exploring development and partnership options for MAT9001, prescription-only omega-3 fatty acid-based composition under development for hypertriglyceridemia.

NOTE B - Going Concern and Plan of Operation

The accompanying financial statements have been prepared in conformity with generally accepted accounting principles, which contemplate continuation of the Company as a going concern.

The Company has experienced net losses and negative cash flows from operations each period since its inception. Through December 31, 2015, the Company had an accumulated deficit of approximately $23.2 million. The Company's operations have been financed primarily through the sale of equity securities. The Company's net loss for the year ended December 31, 2015 was approximately $9.1 million and $10.2 million for the year ended December 31, 2014.

The Company has been engaged in developing 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 products 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 2020 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 for other indications for its lead product candidates and diversifies its R&D portfolio. As a result, the Company expects to continue to incur substantial losses for the foreseeable future, and that these losses will be increasing.

The Company will need to secure additional capital in order to fund operations and to continue and complete its planned clinical and operational activities related to the product candidates and technologies that the Company recently acquired from Aquarius. The Company can provide no assurances that such additional financing will be available to the Company on acceptable terms, or at all. During the third quarter of 2015, the Company instituted cost deferral and savings measures to preserve its cash. The Company has taken steps to reduce and delay expenses through the timing and monitoring of our preclinical animal programs and as well as reducing professional fees, and compensation expenses in the short term. The Company is anticipating that the existing cash balance on hand at December 31, 2015 would be sufficient to meet its operating obligations through July 2016. The Company's recurring losses from operations, and need for additional funding, raise substantial doubt about its ability to continue as a going concern, and as a result, the Company's independent registered public accounting firm included an explanatory paragraph in this report on the Company's financial statements as of and for the year ended December 31, 2015 with respect to this uncertainty.

NOTE C - Summary of Significant Accounting Policies

[1] Basis of Presentation

The accompanying consolidated financial statements include the consolidated accounts of Matinas BioPharma Holdings Inc. "Holdings" and its wholly owned subsidiaries, Matinas BioPharma Inc. and Aquarius Biotechnologies, Inc. the operational subsidiaries of Holdings. 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 subsidiary. All intercompany transactions have been eliminated in consolidation.

[2] 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.

[3] 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.

[4] Concentration of Credit Risk

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents. Cash balances are maintained principally at one major U.S. financial institution and are insured by the Federal Deposit Insurance Corporation ("FDIC") up to regulatory limits. At all times throughout the year ended December 31, 2015, the Company's cash balances exceeded the FDIC insurance limit. The Company has not experienced any losses in such accounts.

[5] 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 ranges from three to ten years. Capitalized costs associated with leasehold improvements are depreciated over the lesser of the useful life of the asset or the remaining life of the lease.

[6] 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 ASC 740-10 and has analyzed its filing positions in 2015 and 2014 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, 2015. In addition, future changes in unrecognized tax benefits will have no impact on the effective tax rate due to the existence of the valuation.

Since the Company incurred net operating losses in every tax year since inception, the 2013, 2014 and 2015 income tax returns are subject to examination and adjustments by the IRS for at least three years following the year in which the tax attributes are utilized.

[7] Stock-Based Compensation

The Company accounts for stock-based compensation to employees in conformity with the provisions of ASC Topic 718, "Stock *Based Compensation"*. Stock-based compensation to employees consist of stock option grants and restricted shares that are recognized in the 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 stockbased 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. If necessary in subsequent periods, an adjustment will be booked if actual forfeitures differ from those estimated. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered stock option or warrant. The Company estimates forfeiture rates for all unvested awards when calculating the expense for the period. In estimating the forfeiture rate, the Company monitors both stock option and warrant exercises as well as employee and non-employee termination patterns.

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.

[8] 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, restricted cash, accounts payable and accrued expenses approximate fair value due to the short-term nature of these instruments.

[9] Earnings Per Share

Basic earnings per common share is computed as net loss divided by the weighted average number of common shares outstanding during the period. Diluted earnings per common share is the same as basic earnings per common share because the Company incurred a net loss during each period presented, and the potentially dilutive securities from the assumed exercise of all outstanding stock options and warrants would have an antidilutive effect. The following schedule details the number of shares issuable upon the exercise of stock options and warrants, which have been excluded from the diluted loss per share calculation for the years ended December 31, 2015 and 2014:

	2015	2014
Stock Options	6,093,000	5,353,417
Warrants	39,250,000	15,250,000
Total	**45,343,000**	**20,603,417**

[10] Revenue Recognition

The Company recognizes revenue from the NIH contracts when the specified performance milestone is achieved. The milestones are analyzed and approved on a monthly basis through progress reports submitted by the Company. The existing NIH contracts ended in 2015.

[11] Research and Development

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 our included as part of General and Administrative expenses.

[12] Recent accounting pronouncements

In September 2015, the FASB issued a new standard simplifying the accounting for measurement-period adjustments. The new standard eliminates the requirement to restate prior period financial statements for measurement period adjustments. The new standard requires that the cumulative impact of a measurement period adjustment (including the impact on prior periods) be recognized in the reporting period in which the adjustment is identified. The standard is effective for interim and annual periods beginning after December 15, 2015 and is not expected to have a material impact on our financial condition or results of operations.

In November 2015, the FASB issued a new standard simplifying the classification of deferred tax assets and liabilities. The new standard requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. The standard is effective for interim and annual periods beginning after December 15, 2016 and allows for early adoption using a full retrospective method or a prospective method. We have elected to early adopt the provisions of this new standard using a prospective method. As a result, all deferred taxes as of December 31, 2015 are classified as noncurrent in our consolidated balance sheet, while prior periods remain as previously reported. As of December 31, 2015 there are no deferred tax assets.

In 2014, the FASB issued ASU 2014-15, “Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern.” This ASU describes how an entity should assess its ability to meet obligations and sets rules for how this information should be disclosed in the financial statements. The standard provides accounting guidance that will be used along with existing auditing standards. The ASU is effective for interim and annual periods beginning after December 15, 2016. Early application is permitted. The Corporation is in the process of evaluating the impact of this standard but does not expect this standard to have a material impact on the Corporation’s consolidated financial position or results of operation.

[13] 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.

The Company's intangible assets are comprised of acquired in-process research and development, or IPR&D. The fair value of IPR&D acquired through a business combination is capitalized as an indefinite-lived intangible asset until the completion or abandonment of the related research and development activities. IPR&D is tested for impairment annually or when events or circumstances indicate that the fair value may be below the carrying value of the asset. There was no impairment for the year ended December 31, 2015. If and when research and development is complete, the associated assets would then be amortized over their estimated useful lives.

[14] 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 the two-step goodwill impairment test 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, the two-step goodwill impairment test 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. In fiscal year 2015, we assessed goodwill impairment by performing a qualitative test for our reporting unit. Based on the results of our testing, it was determined that it is more-likely-than-not that the fair value of the reporting units are greater than their carrying amounts. There was no impairment of goodwill in fiscal year 2015.

We review 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 (i.e. > 50% chance) 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. Our indefinite-lived intangible assets are IPR&D intangible assets. In all other instances we used the qualitative test and concluded that it was more-likely-than-not that all other indefinite-lived assets were not impaired and therefore, there were no impairments in fiscal year 2015.

[15] Reclassification

Contingent consideration arising from the acquisition of Aquarius is included as part of the purchase price and is recognized at fair value as of the acquisition date. See Note D below. During the quarter ended December 31, 2015, we reclassified the contingent consideration ($ 753 thousand) valued at the time of the Aquarius Acquisition (see Note D), from a long term liability to additional paid in capital in equity. We also reclass $48 thousand of deferred tax liability as an offset to goodwill. These reclassifications were made as a measurement period adjustment after we finalized the purchase price allocation for the Aquarius Acquisition consummated in January 2015.

NOTE D – Acquisition of Aquarius Biotechnologies, Inc.

On January 29, 2015, we entered into the Merger Agreement with Aquarius, Saffron Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of ours ("Merger Sub") and J. Carl Craft, as the stockholder representative. The merger contemplated by the Aquarius Merger became effective on January 29, 2015, following the satisfaction or waiver of the conditions described in the Merger Agreement, including approval of the transaction by 100% of Aquarius' stockholders. Pursuant to the Aquarius Merger, the Merger Sub merged with and into Aquarius, with Aquarius surviving the merger as a wholly-owned subsidiary of ours.

Pursuant to the terms of the Merger Agreement, we were obligated to issue an aggregate of up to 5,000,000 shares of our common stock at closing, subject to adjustment as set forth in the Merger Agreement. At closing, we issued 4,608,020 shares (the "Closing Shares") of our common stock as closing consideration. In addition, subject to our right of setoff for indemnification claims, we may issue up to an additional 3,000,000 shares (the "Additional Shares") of our common stock upon the achievement of certain milestones. The milestone consideration consists of (i) 1,500,000 shares issuable upon the dosing of the first patient in a phase III trial sponsored by us for a product utilizing Aquarius' proprietary cochleate delivery technology and (ii) 1,500,000 shares issuable upon FDA approval of the first NDA submitted by us for a product utilizing Aquarius' proprietary cochleate delivery technology. As discussed in footnote (15) the Company ultimately concluded that the contingent share issuance represented equity settled contingent consideration and as such have reclassified the amounts to equity as of December 31, 2015.

The transaction was accounted for as a business combination, and accordingly the Company has included the results of operations of Aquarius subsequent to the January 29, 2015 closing date. The transaction resulted in a significant amount of in-process research and development, goodwill and deferred tax liability on the balance sheet, as detailed below.

The acquisition-date fair value of the consideration transferred totaled $2,873,035 as of January 29, 2015 and consisted of the following items:

Fair value of 4,608,020 of common stock issued at a price per share of $0.46 as of January 29, 2015 the closing date of the merger.	$ 2,119,689
Fair value of potential Matinas common stock as contingent consideration that will be issued upon achieving certain future clinical milestone-(a)	422,609
Fair value of potential Matinas common stock as contingent consideration that will be issued upon achieving certain future regulatory milestone-(a)	330,737
Total consideration	$ 2,873,035

(a)-Reflects recognition of the estimated fair value of the contingent consideration payable with issuance of Matinas common stock upon achievement of certain future clinical and regulatory milestones, the achievement of which is uncertain. The fair value of the additional shares were established by assigning probabilities and projected dates of positive outcome for the milestones and valuing the future issuance of the shares by using the Black-Scholes options pricing model to account for the uncertainty in the future value of the shares. The value of the shares as derived using the options pricing model were then weighted based on the probability of achieving the milestones to determine the fair market value of the additional shares. See footnote C-15 for additional details.

The allocation of the total purchase price is described below based on the estimated fair value of the assets acquired and liabilities assumed on the date of the acquisition.

Cash	$ 70,754
Contract/ Grant receivable	45,644
Prepaid expenses and other current assets	5,084
Equipment, net	5,051
Other assets	700
In-process research and development-(b)	3,017,377
Total identifiable assets	3,144,610
Accounts payable	300,413
Notes payable-(d)	10,000
Accrued expenses	92,509
Total liabilities assumed	402,922
Net identifiable assets acquired	2,741,688
Goodwill-(c)	1,336,488
Deferred income taxes arising from basis differences of tax aspects of in-process research and development	(1,205,141)
Net assets acquired	$ 2,873,035

(b)-The fair value of the in-process research and development asset was estimated on the basis of its replacement cost as determined by a buildup of the costs incurred to develop the technology as it existed as of the acquisition date resulting in a fair value of $3,017,377. The fair value of other assets and liabilities approximate their book value.

(c)-The Company allocated the purchase price to the net tangible and intangible assets based upon their estimated fair values at the Merger date. The excess of the purchase price over the estimated fair values of the net tangible and intangible assets acquired has been recorded as goodwill including deferred tax liabilities resulting from the tax attributes of the in-process research and development (see Note C 14). In connection with the Aquarius acquisition, the Company made an adjustment as a result of the purchase accounting requirements to reflect a change in the value of the deferred tax liabilities resulting from an adjustment to the Company's effective tax rate, recording a $48 thousand reduction to the deferred tax liabilities with an offsetting credit to Goodwill.

(d)- Aquarius issued a note for a loan that was made to a related party. Interest on the note is calculated using the applicable federal rate for midterm loans. Since the note has no specified repayment terms, it is considered a current liability. This note was paid in full in 2015.

NOTE E – 2015 Private Placement Funding

The Company had two closings for a private placement, on March 31, 2015 and April 10, 2015, respectively.

This private placement offered to accredited investors (the "Offering") of the Company's units (the "Units") at a price of $0.50 per Unit, with each Unit consisting of: (i) one share of the Company's common stock, par value $0.0001 per share ("Common Stock"), and (ii) a five-year warrant to purchase one share of common stock at an exercise price of $0.75 per share ("Warrants"). The Warrants are callable by the Company following the effectiveness of the registration statement covering the resale of the shares of common stock underlying the Warrants (which occurred on July 23, 2015) if the closing bid price for the Company's common stock is at or above $3.00 per share for the twenty (20) consecutive trading days immediately prior to such a call and provided that the registration statement is current at the time.

In connection with the Offering, the Company also entered into definitive subscription agreements (the "Subscription Agreements") with accredited investors (the "Investors") and issued an aggregate of 20,000,000 Units in the Offering, consisting of an aggregate of 20,000,000 shares of common stock and Warrants to purchase an aggregate 20,000,000 shares of common stock for aggregate gross proceeds to the Company of $10 million and net proceeds of approximately $8.5 million after paying expenses after deducting the placement agent fees described below and other estimated Offering expenses.

In addition, the Company entered into a Registration Rights Agreement with the Investors pursuant to which the Company has granted the Investors certain registration rights which are described in more detail below.

The Company entered into a Placement Agency Agreement with Aegis Capital Corp. ("Aegis") pursuant to which Aegis acted as the Company's exclusive placement agent (the "Placement Agent") for the Offering. Immediately prior to the Offering, the Placement Agent and its affiliates beneficially owned an aggregate of more than 10% of our outstanding equity securities. In addition, Adam Stern, Head of Private Equity Banking at Aegis, is a member of the Company's board of directors. Pursuant to the terms of the Placement Agency Agreement, in connection with the Offering, the Company paid the Placement Agent an aggregate cash fee of $1,000,000 and non-accountable expense allowance of $300,000 through April 2015 and issued to the Placement Agent and its designees warrants (substantially similar to the Warrants) to purchase 2,000,000 shares of common stock at $0.50 per share and additional warrants to purchase 2,000,000 shares of common stock at $0.75 per share. In addition, the Company has agreed to engage the Placement Agent as our warrant solicitation agent in the event the Warrants are called for redemption and shall pay a warrant solicitation fee to the Placement Agent equal to five (5%) percent of the amount of funds solicited by the Placement Agent upon the exercise of the Warrants following such redemption.

Registration Rights Agreement

In connection with the 2015 Private Placement, the Company entered into a registration rights agreement with the investors in the 2015 Private Placement pursuant to which the Company was required to file a registration statement covering the resale of the shares of common stock and the shares of common stock underlying the warrants within sixty days and to use commercially reasonable efforts to have the registration statement declared effective within 150 days. The Registration Statement was filed on June 9, 2015 and declared effective on July 23, 2015. The Company is required to keep the registration statement continuously effective under the Securities Act of 1933, as amended (the "Securities Act"), for a period of one year from the date it is declared effective by the SEC or for such shorter period ending on the earlier of the date when all the registrable securities covered by the registration statement have been sold or such time as all of the securities covered by the registration statement can be sold under Rule 144 without any volume limitations (the "Effectiveness Period"). If the Company does not maintain the effectiveness of the registration statement during the Effectiveness Period, subject to certain limitations and the right of the Company to suspend the use of the prospectus for certain periods, the Company shall pay to each holder of registrable securities purchased in 2015 Private Placement an amount in cash equal to half of one percent (0.5%) of such holder's investment amount, subject to a maximum penalty equal to six percent (6%) of such holder's investment amount, on every thirty (30) day anniversary of such failure to maintain the registration statement until such failure was cured; provided however that such liquidated damages shall be paid only with respect to registrable securities that cannot then be immediately resold in reliance on Rule 144. The Company has determined that as of December 31, 2015 there is no liability associated with the registration rights agreement.

NOTE F – Equipment

Fixed assets, summarized by major category, consist of the following ($ in thousands) for the year ended:

	December 31, 2015	December 31, 2014
Lab Equipment	**$ 327**	**245**
Furniture and Fixtures	**20**	**20**
Capitalized Leased Equipment	**111**	**111**
Leasehold Improvements	**7**	7
Total	**465**	**383**
Less accumulated depreciation	**87**	**43**
Equipment, net	**$ 378**	**$ 340**

In 2014, the company entered a 24-month capital lease for lab equipment which has a buyout option of $1 at the end of lease. This lease was capitalized. The payments under the lease will be accounted for as interest and payments under capital lease using 2-year amortization. During the years ended December 31, 2015 and 2014, the Company recognized interest expense of $ 885 and $ 1,379, respectively associated with the lease payments. Depreciation expense for the years ended December 31, 2015 and 2014 was approximately $44 thousand and $42 thousand, respectively.

NOTE G - Stock Holders Equity

Warrants

As of December 31, 2015, the Company had outstanding warrants to purchase an aggregate of 39,250,000 shares of common stock at exercise prices ranging from $0.50 to $2.00 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. All of the Warrants may be exercised on a "cashless" basis in certain circumstances. However, since all such cashless exercises are settled on a net share basis, the exercise price and the number of warrant shares purchasable upon the exercise of the Investor Warrants are subject to adjustment upon the occurrence of certain events, which include stock dividends, stock splits, combinations and reclassifications of the Company capital stock or similar "organic changes" to the equity structure of the Company. Accordingly, pursuant to ASC 815, the warrants are classified as equity in the accompanying statement of stockholder's Equity.

The Company may call the Warrants, other than the Placement Agent Warrants, at any time the common stock trades above $5.00 (for 13 million warrants issued in 2013) or 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. Such term is a contingent feature and within the control of the Company, therefore does not require liability classification.

A summary of equity warrants outstanding as of December 31, 2015 is presented below, all of which are fully vested.

	Shares
July 11, 2013 formation of Holdings, 4,000,000 warrants issued, terms 5 years, exercisable at $2.00, including 250,000 warrants sold to Mr. Adam Stern	4,000,000
July 11, 2013 recapitalization of Matinas BioPharma Inc. 1,000,000 warrants issued, terms 5 years, exercisable at $2.00	1,000,000
July and August 2013 completion of Private Placement, 7,500,000 warrants issued, terms 5 years, exercisable at $2.00	7,500,000
July 30, 2013 Placement Agent warrants issued as part of compensation for Private Placement. Terms 5 years, exercisable at $2.00	750,000
July 30, 2013 Placement Agent warrant issued as part of compensation for Private Placement. Terms 5 years exercisable at $1.00	1,500,000
July 30, 2013 500,000 warrants sold to Chairman of Board Mr. Herb Conrad for $20,000. Terms 5 years, exercisable at $2.00 per share	500,000
March 31, 2015 Warrants:	
March 31, 2015 first close of Private Placement, 9,875,0000 warrants issued, terms 5 years, exercisable at $0.75	9,875,000
March 31, 2015, Placement Agent Warrants, 987,500 issued, terms 5 years, exercisable at $0.75	987,500
March 31, 2015, Placement Agent Warrants, 987,500 issued, terms 5 years, exercisable at $ 0.50	987,500
April 10, 2015 Warrants:	
April 10, 2015 first close of Private Placement, 10,125,000 warrants issued, terms 5 years, exercisable at $0.75	10,125,000
April 10, 2015, Placement Agent Warrants, 1,012,500 issued, terms 5 years, exercisable at $0.75	1,012,500
April 10, 2015, Placement Agent Warrants, 1,012,500 issued, terms 5 years, exercisable at $0.50	1,012,500
Total Warrants Outstanding at December 31, 2015	39,250,000

NOTE H - 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. The Company currently has reserved 9,541,706 shares of common stock 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 ($ in thousands):

	Year Ended December 31,	
	2015	2014
Research and Development	$ 528	$ 398
General and Administrative	1,064	1,576
Total	$ 1,592	$ 1,974

Stock Incentive Plans:

The following table contains information about the Company's stock plan at December 31, 2015:

	Awards Reserved for Issuance	Awards Issued	Awards Available for Grant
2013 Equity Compensation Plan	9,541,706	7,474,434*	2,067,272

* includes both stock grants and option grants

The following table summarizes the Company' stock option activity and related information for the years ended December 31, 2014 and 2015 (number of options in thousands):

	Number of Options	Weighted average exercise price	Weighted average contractual term in years
Outstanding at December 31, 2013	3,160	$ 0.94	9.7
Granted	2,413	$ 1.22	
Exercised	-		
Forfeited	(196)	0.94	
Expired	(24)	0.96	
Outstanding at December 31, 2014	5,353	$ 1.06	9.1
Granted	1,960	$ 0.56	
Exercised	-		
Forfeited	(217)	0.95	
Expired	(193)	0.89	
Outstanding at December 31, 2015	6,903	$ 0.93	8.4

	Year ended December 31,	
	2015	2014
Options exercisable at end of year	3,752	2,460
Weighted average grant date fair value (per share) of options granted during the period	$ 0.65	$ 0.68

All options expire ten years from date of grant. Except for options granted to consultants, all remaining options vest entirely and evenly over three 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.

The Company recognizes 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. The following weighted-average assumptions were used to calculate share based compensation for the full year ended:

	For the year ended December 31,	
	2015	2014
Volatility	71.10 % - 102.3%	68.76%
Risk-free interest rate	1.34% - 1.74%	1.65% - 1.93%
Dividend yield	0.0%	0.0%
Expected life	6.0 years	4.75 – 5.5 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 was determined by examining the historical volatilities for industry peers, as the Company has limited history for the Company's common stock. The Company will continue to analyze the historical stock price volatility and expected term assumptions as more historical data for the Company's 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 the Company's stock options.

The expected dividend assumption is based on the Company's history and expectation of dividend payouts. The Company has never paid dividends on its common stock and does not anticipate paying dividends on its common stock in the foreseeable future. Accordingly, the Company has assumed no dividend yield for purposes of estimating the fair value of the Company share-based compensation.

The Company estimates the forfeiture rate at the time of grant and revisions, if necessary, were estimated based on management's expectation through industry knowledge and historical data.

During the years ended December 31, 2015 and 2014, the Company issued 278,784 and 292,650 shares of restricted common stock to certain board of directors, officers and consultants, respectively and recorded approximately $0.2 million and $0.2 million to stock based compensation, respectively.

During the years ended December 31, 2014, the company met certain clinical milestones upon which 71,750 performance based options vested and the Company recorded approximately $28,000 of stock based compensation. No additional milestones were achieved during the year ended December 31, 2015.

As of December 31, 2015, the aggregate intrinsic value of in the money options was $0.6 million. The total intrinsic value is calculated as the difference between the Company's stock price on December 31, 2015 and the exercise price, multiplied by the number of in-the-money options that would have been received by the option holders had all option holders exercised their options on the last trading day of the fiscal year. This amount changes based on the fair market value of the Company's shares.

As of December 31, 2015, there was approximately $1.9 million of unrecognized compensation costs, net of estimated forfeitures, related to stock option awards to employees, which is expected to be recognized over a remaining weighted average period of 1.3 years.

NOTE I – COMMMITMENTS

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 $12,723, increasing to approximately $14,200 per month toward the end of the term. The Company records rent expense on a straight-line basis. Rent expense for the years ended December 31, 2015 and 2014 was $211,500 and $95,000, respectively.

In December of 2015, the Company renewed its agreement to lease laboratory space for one year starting January 1, 2016 in Monmouth Junction, New Jersey at a monthly rent of $2,287.

Listed below is a summary of future lease rental payments:

Fiscal Year Ending December 31,	Lease Commitments
2016	184,520
2017	160,012
2018	162,948
2019	165,896
2020 and beyond	252,764
Total future minimum lease payments	$ 926,140

The Company was obligated to provide a security deposit of $300,000 to obtain lease space. This deposit was reduced by $100,000 in 2015 and can be reduced by $ 100,000 on an annual basis going forward, down to $50,000, as long as the Company makes timely rental payments.

Through our acquisition of Aquarius, 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) 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.

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 J – 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, 2015 and December 31, 2014, 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.

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:

	Years ended December 31,	
	2015	**2014**
Percent of pre-tax income:		
U.S. federal statutory income tax rate	34.0%	34.0%
State taxes, net of federal benefit	0.0%	0.1%
Permanent items	(5.3)%	(3.1)%
Research and development credit	3.0%	0.9%
Change in valuation allowance	(31.7)%	(31.9)%
Effective income tax rate	0.0%	0.0%

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 2015 and 2014 consist of the following:

	As of December 31,	
	2015	**2014**
Deferred tax assets (liabilities)		
Share-based compensation	$ 518,542	$ 489,017
Depreciation and amortization	37,186	73,894
Warrants	43,997	43,997
Accrued liability	118,386	-
Net operating loss carryforwards	7,093,015	4,379,541
Federal research and development credit carryforwards	525,001	241,318
In process research and development	(1,205,141)	-
Deferred income tax assets	7,130,986	5,227,767
Valuation allowance	(8,336,127)	(5,227,767)
Net deferred tax liabilities	$ (1,205,141)	$ 0

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 $8.3 million and $5.2 million as of December 31, 2015 and 2014, respectively, representing an increase of $3.1 million.

As of December 31, 2015, the Company had Federal net operating loss carryforwards of $ 19.2 million. The Company also had federal and state research and development tax credit carryforwards of $525,000. The federal net operating loss and tax credit carryforwards will expire at various dates beginning in 2033, if not utilized. The difference between the statutory tax rate and the effective tax rate is primarily attributable to the valuation allowance offsetting deferred tax assets

In December 2015, the Company recognized a tax benefit of approximately $760,000 in connection with the sale of state net operating losses and state research and development credits to a third party under the New Jersey Technology Business Tax Certificate Program.

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.

There was a change in accounting principle related to our early adoption of ASU 2015-17 on a prospective basis as of December 31, 2015. The adoption did not result in any increase or decrease to the Company's current or noncurrent assets or liabilities. The adoption of the ASU to classify all of our deferred tax assets and liabilities as noncurrent will reduce time, complexity and costs to prepare our tax disclosures related to deferred income taxes.

Exhibit 21.1

Subsidiaries of Matinas BioPharma Holdings, Inc.

Name	State of Incorporation
Matinas BioPharma, Inc.	Delaware
Aquarius Biotechnologies, 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. on Form S8 (File No. 333-203141) and Registration Statement Form S8 (File No. 333-198488) of our report dated March 30, 2016, on our audits of the consolidated financial statements as of December 31, 2015 and 2014, which report is included in this Annual Report on Form 10-K. Our report includes an explanatory paragraph about the existence of substantial doubt concerning the Company's ability to continue as a going concern.

/s/ EisnerAmper LLP

Iselin, New Jersey
March 30, 2016

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Roelof Rongen, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2015 of Matinas BioPharma Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2016

/s/ Roelof Rongen
Roelof Rongen
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Gary Gaglione, certify that:

1. I have reviewed this annual report on Form 10-K for the year ended December 31, 2015 of Matinas BioPharma Holdings, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2016

/s/ Gary Gaglione
Gary Gaglione
Acting 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, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Roelof Rongen, Chief Executive Officer of the Company, and Gary Gaglione, Acting Chief Financial Officer of the Company, hereby certify, to the knowledge of the undersigned, pursuant to 18 U.S.C. Section 1350, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2016

/s/ Roelof Rongen
Roelof Rongen
Chief Executive Officer
(Principal Executive Officer)

Date: March 30, 2016

/s/ Gary Gaglione
Gary Gaglione
Acting 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.

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