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, 2014

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 July 21, 2014 was approximately $23.2 million. The registrant has provided this information as of July 21, 2014 because its common stock was not publicly traded as of the last business day of its most recently completed second fiscal quarter.

As of March 20, 2015 there were 36,900,670 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, 2014

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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 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 ability to integrate our recent acquisition of Aquarius Biotechnologies, Inc.;
- 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, 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 lack of a sales and marketing organization and our ability to commercialize products, if we obtain regulatory approval;
- our dependence on third-parties, including third-parties to manufacture and third-party CROs to conduct our clinical trials;
- our ability to maintain or protect the validity of our patents and other intellectual property;
- our ability to retain key executive members;
- our ability to internally develop new inventions and intellectual property;
- interpretations of current laws and the passages of future laws;

- 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

On January 29, 2015, we completed the acquisition of Aquarius Biotechnologies Inc., (referred to as the "Aquarius Merger" throughout this document and which is discussed in more detail under "Recent Developments"), 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 the development of targeted therapeutics using our innovative lipid-based drug delivery platform with an initial focus on the treatment of serious fungal and bacterial infections and the development of lipid-based prescription therapeutics for the treatment of cardiovascular and metabolic conditions.

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. 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.

Our lead product candidate for the treatment of infectious diseases is MAT 2203, an oral formulation of a broad spectrum anti-fungal drug called amphotericin B using our acquired cochleate delivery technology, for which a single-dose Phase 1a study has been completed. We expect to commence and complete 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, in 2015, with results expected in the fourth quarter of 2015. We are developing a pipeline of oral products by applying our cochleate delivery technology to a potentially broad array of established pharmaceuticals, including MAT 2501, an application of our cochleate delivery technology to a 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. We also continue to focus on identifying and developing novel pharmaceutical lipid-based products, including MAT9001 with an initial indication for the treatment of highly elevated triglycerides, or severe hypertriglyceridemia. Finally, our MAT8800 discovery program is seeking to identify and develop product candidates derived from omega-3 fatty acids for the treatment of non-alcoholic fatty liver disease for which there are currently no therapeutic solutions available.

Strategy

Our goal is to become a fully integrated biopharmaceutical company that discovers, develops and commercializes novel anti-infective medicines and treatments for cardiovascular and metabolic conditions for use in areas of unmet medical need. Key elements of our strategy include:

- Build a significant portfolio of pharmaceutical products using our proprietary cochleate delivery technology platform in conjunction with pharmacologically active compounds, such as amphotericin B and amikacin, 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;
- Focus on the development of our anti-infective product candidates, including commencing and completing the planned Phase2a clinical trial with MAT2203 to be conducted in cooperation with and funded by the NIH, with results expected in the fourth quarter of 2015 and advancing MAT2501 into clinical studies by completing animal studies and filing an Investigational New Drug Application, or IND, with the Food and Drug Administration, or FDA, during 2015;
- Continue to develop our cardiovascular therapeutic candidates, including completing the current PK/PD study with MAT9001 in Canada in 2015, which has the goal of determining superior bioavailability and enhanced efficacy over a leading therapy for hypertriglyceridemia, and developing a product candidate resulting from our MAT8800 discovery program for the treatment of non-alcoholic fatty liver disease;

- Continue and expand collaborations with non-commercial organizations for scientific expertise and funding support, such as the NIH; and
- Build a commercial organization which will give us the opportunity to retain marketing rights to our product candidates and commercialize such products ourselves, particularly where a product has a niche market that we could address through a focused specialized sales force.

Our Anti-Infective Product Candidates

MAT2203

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, administered as an oral solution is not widely available, is not very effective, and irritates the oral and esophageal tissues.

Our lead anti-infective product candidate, MAT 2203, 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 echynocandins, 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.

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.

Development History of MAT2203

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

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 planned Phase 2a human efficacy studies, 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 adverse events reported. We expect to commence a Phase 2a study for MAT 2203 in collaboration with, and funded by, the NIH in the second quarter of 2015. We are currently finalizing protocols with the NIH for the Phase 2a study of MAT 2203.

MAT2501 – Targeting Multi-Drug Resistant Gram Negative Bacteria

We are initially focused on developing product candidates with application in infectious diseases, including MAT 2501 for treating severe, hospital-acquired infections, including gram-negative bacterial infections.

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 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 of the antibiotics that cover or are focused on the treatment of Gram-negative bacteria 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 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 both IV dosage and oral dosage form.

MAT2501

MAT 2501 is an application of our cochleate delivery technology to a broad spectrum IV-delivered antibiotic called amikacin, which is an aminoglycoside antibiotic most often used for treating severe, hospital-acquired infections, including gram-negative bacterial infections. We believe that MAT 2501 has the potential to fulfill a significant need to treat life-threatening Gram-negative bacterial infections by providing for a potential opportunity to deliver amikacin orally, which we believe may be more effective and less toxic than the currently available IV-administered product. We are developing MAT 2501 in collaboration with the NIH. Proof of principle testing of MAT 2501 in animal models demonstrated in vivo efficacy of orally administered amikacin without toxicity or side effects associated with IV administered amikacin.

The lipid-crystal nano-particle formulation of amikacin in MAT2501 contains the medication in solid particles for targeted transportation to the site of infection in the body. Thus, MAT2501 is expected to be highly differentiated based on its oral formulation and tissue-targeted delivery of an IV-only medication and excellent tolerability and safety, believed to potentially eliminate kidney and hearing damage and allow treatment of patients with significant renal impairment and sensitive neural tissues. MAT2501 is currently undergoing formal pre-clinical animal toxicology studies under NIH supervision and sponsorship, in preparation for filing an IND later in 2015. It is our goal to develop MAT2501 for the treatment of serious bacterial infections, such as drug-resistant gram-negative infections.

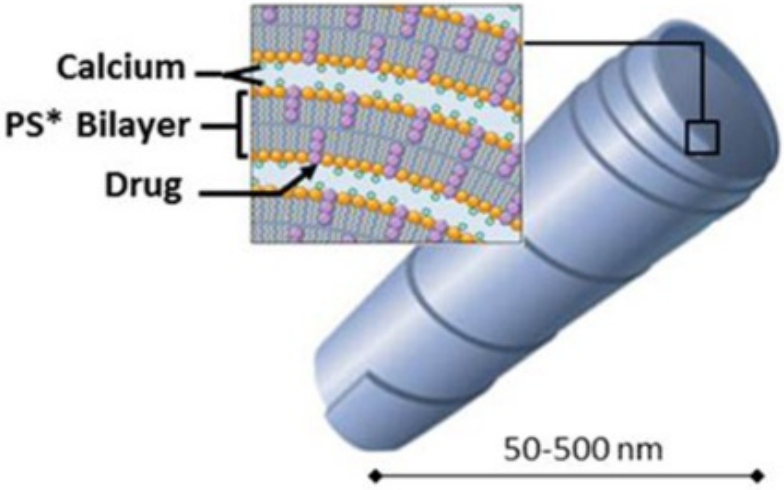
Our Cochleate Delivery Technology

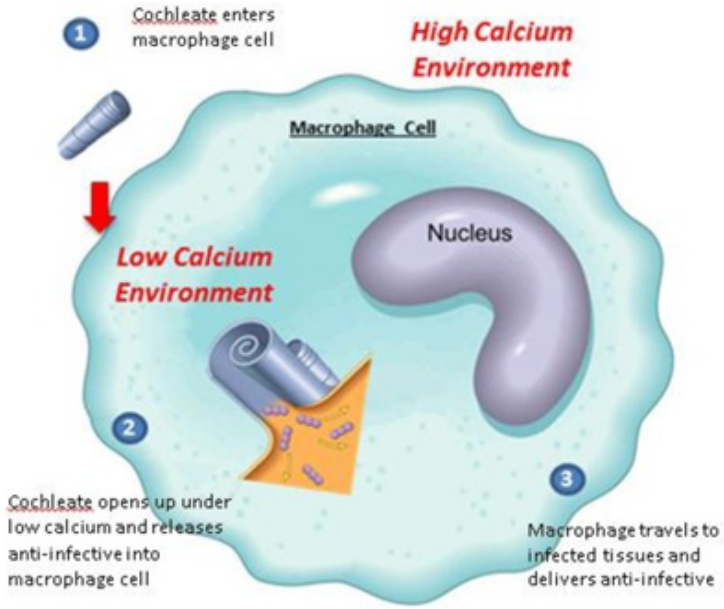
Our core capabilities combine the use of lipids as active pharmaceutical ingredients (API) and the use of lipids in “cochleate-shaped” lipid-crystal nano-particle drug delivery vehicles. Therapeutic applications of our proprietary delivery technology are focused on the delivery of several potent and 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. In

Our lipid-based delivery technology encapsulates 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 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 lipid-crystal cochleate particles 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.

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, atovaquone and meropenem. By way of example, we are collaborating with NIH on the pre-clinical development of oral capreomycin using our cochleate delivery technology for the treatment of certain strains of tuberculosis.

Our Cardiovascular Therapeutic Candidates

MAT9001

Our lead cardiovascular product candidate, MAT9001, is a proprietary prescription-only omega-3 fatty acid composition, comprised of a complex mixture of omega-3 fatty acids, including eicosapentaenoic acid, or EPA, docosapentaenoic acid, or DPA, several other omega-3 fatty acids, and relatively nominal amounts of docosahexaenoic acid, or DHA, and non-omega-3 fatty acids. We believe that based upon MAT9001's unique composition, which includes more DPA than other known omega-3 fatty acids, it will prove to be differentiated from other existing therapies for the treatment of very high triglycerides, or severe hypertriglyceridemia, and dyslipidemia. Triglycerides are fats that are carried in the blood, together with cholesterol, within lipoproteins. High levels of triglyceride rich lipoproteins are associated with an increased risk of atherosclerotic cardiovascular disease and in the case of severe hypertriglyceridemia, acute pancreatitis. High levels of triglycerides are due to both genetic and environmental factors and are associated with comorbid conditions such as diabetes, chronic renal failure and nephrotic syndrome. Unlike the current approved therapies in this product category, many of which have been repurposed following clinical failures in their originally intended indications, we have specifically designed and developed MAT9001 to treat severe hypertriglyceridemia and dyslipidemia. We believe that the results of these targeted development activities and related clinical investigations may yield an improved therapeutic profile compared to the currently-existing therapies, characterized most importantly by MAT9001's differentiating mechanistic features associated with its unique high DPA composition and enhanced potency. Importantly, in December 2014 we were granted a U.S. patent for the use of DPA to treat hypertriglyceridemia.

We are primarily focused on developing and commercializing MAT9001 through approval by the FDA, with an initial indication for the treatment of severe hypertriglyceridemia. Severe hypertriglyceridemia refers to a condition in which patients have high blood levels of triglycerides (TG ≥ 500 mg/dl) and is recognized as an independent risk factor for pancreatitis and cardiovascular disease. Based on information provided by the National Heart, Lung and Blood Institute and National Cholesterol Education Program ("NCEP") ATP III Guidelines (collectively, the "NCEP Guidelines"), we estimate that more than 7 million people in the United States have severe hypertriglyceridemia. If we receive FDA approval for severe hypertriglyceridemia, we may seek approval for use of MAT9001 in additional indications, including the treatment of patients with mixed dyslipidemia who are already undergoing treatment with a statin, a commonly used class of cholesterol lowering medications. Mixed dyslipidemia refers to a condition in which patients have a combination of both elevated triglycerides (≥200mg/dl), and elevated cholesterol levels. According to the NCEP Guidelines, we estimate that approximately 30 to 35 million Americans have mixed dyslipidemia.

Currently Available Treatment Options and Market Opportunity

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

The treatment rate of hypertriglyceridemia has remained relatively low – below ten percent - compared to the adult population with hypertriglyceridemia according to the NCEP Guidelines and data released by IMS Health. Historically, fibrates such as gemfibrozil (Lopid) and fenofibrate (Tricor or Trilipix) have led the class of treatments of hypertriglyceridemia. However, due to their inability to establish clinical outcome benefits and their limited compatibility with statin therapy, the fibrate utilization rate has remained relatively low and is currently declining. Other products used to treat severe hypertriglyceridemia incorporating niacin as the active pharmaceutical ingredient have not been able to establish additional outcome benefits as compared to statin treatment alone, and are also encountering declining utilization according to data released by IMS Health and a recent article published by the NCBI, entitled "*Utilization patterns of extended-release niacin in Canada: Analysis of an administrative claims database*." Because of their lack of outcome benefits, fibrate and niacin use has been mostly concentrated in severe hypertriglyceridemia.

Many omega-3 fatty acid based products have anti-thrombotic and anti-inflammatory effects that suggest effectiveness in inhibiting atherosclerosis in animal models as well as reducing the rate of adverse cardiovascular events in humans at high risk for such events as demonstrated in the Japan EPA Lipid Intervention Study ("JELIS") and the GISSI Prevenzione trial in Italy. Futhermore, omega-3 fatty acid based products, either concentrates of both EPA and DHA or EPA alone, have been demonstrated in multiple clinical trials to lower serum concentrations in patients with hypertriglyceridemia. In a study published in the New England Journal of Medicine in July 2012 entitled "*n-3 Fatty Acids and Cardiovascular Outcomes in Patients with Dysglycemia*," increased levels of EPA and DHA in red blood cells directly correlated with significant reductions in cardiovascular health risks. However, omega-3 fatty acid based medications with significant levels of DHA have been shown to increase LDL-cholesterol levels, which is a negative side effect.

The global prescription omega-3 market has been growing steadily over the last two decades and we estimate the market currently is approaching $2 billion in global sales. The leading omega-3 prescription pharmaceutical products currently approved for the treatment of hypertriglyceridemia are GlaxoSmithKline's Lovaza (omega-3-acid ethyl esters, an omega-3 mixture containing mostly EPA and DHA, branded as Omacor in the rest of the world), Omacor and Seacor, very similar to Lovaza and marketed in Europe; and Mochida Pharmaceutical Co., Ltd's ("Mochida") Epadel (98% ethyl eicosapentaenoate), the leading Japanese omega-3 product. Recently, a new omega-3 based medication, Amarin's Vascepa (97% ethyl eicosapentaenoate), was approved and launched in the United States.

Differentiation Strategy

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

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

2. MAT9001 is designed to have a highly concentrated potency versus other omega-3 products due to its improved formulation.

We believe that based upon both publicly available pre-clinical and human data associated with one of the key omega-3 components contained in MAT9001, our product will likely:

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

- Better control triglyceride levels; and

- Produce aspirin-like anti-coagulatory effects.

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

Development History

We believe we have optimized the manufacturing process for the active pharmaceutical ingredient of MAT9001 and have completed various preclinical studies with the MAT9001 active ingredient. We completed the first preclinical studies of MAT9001 during the fourth quarter of 2013 with others completed during 2014. In the fourth quarter of 2014, we initiated a pharmacokinetic and pharmacodynamics study (referred to herein as the "PK/PD Study") of MAT9001 in patients with triglycerides in the range of 200 to 400 mg/dL ("high triglycerides"). The PK/PD Study was designed to evaluate approximately 50 patients with high triglycerides with a goal of demonstrating better bioavailability than a leading prescription hypertriglyceridemia product. In addition, we expect this study will provide data on MAT9001's ability to yield distinctive therapeutic response properties and an improved therapeutic profile consistent with its preclinical studies. In March 2015, upon a scheduled interim review of the study data the Steering Committee for this study recommended that the trial has significant power and that no further subjects need to be enrolled to demonstrate the study endpoints. The trial has enrolled 42 subjects to date. We will complete the per-protocol treatment regimen for the enrolled subjects. We expect to report topline data from the PK/PD study in the second quarter of 2015.

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. Previously, we had planned to initiate and complete each of these studies concurrently with a Phase III clinical study for MAT 9001. 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. Following completion of these studies and expected dialogue with FDA, we plan to evaluate the feasibility of continuing our MAT 9001 development program and determine whether to proceed with the additional studies.

MAT8800

We have established a discovery program called MAT8800 to identify and develop a product candidate derived from omega-3 fatty acids for the treatment of non-alcoholic fatty liver disease for which there are currently no therapeutic solutions.

From the scientific literature, it is well established that omega-3 fatty acids interact with a broad range of nuclear receptors, such as PPAR-alpha and PPAR-gamma. We believe that unique combinations of certain omega-3 fatty acids will act as an agonist on another nuclear receptor known as the farnesoid-X receptor (FXR). Activation of FXR has been shown to play a key role in the metabolic pathways relevant to non-alcoholic steato hepatitis, or NASH, highlighting FXR as a potential drug target for the treatment of the disease. Furthermore, activation of FXR induces anti-fibrotic, anti-inflammatory, anti-steatotic and other mechanisms that are necessary for the normal regeneration of the liver and which may play a role in the treatment of more prevalent liver diseases, such as NASH. Our own development work has indicated that certain omega-3 fatty acids may yield improvement in liver enzyme levels and liver histology and may also interact with FXR. Accordingly, we have identified potential omega-3 fatty acid compositions to study in preclinical settings and, in late 2014, we commenced pre-clinical animal studies with several compositions. We expect these studies to be completed during the second or third quarter of 2015.

Recent Developments

Acquisition of Aquarius Biotechnologies

On January 29, 2015, we entered into an 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 ours ("Merger Sub") and J. Carl Craft, as the stockholder representative. Aquarius is a clinical-stage biopharmaceutical company focused on the development and commercialization of new therapies using its innovative drug delivery platform with an initial focus on applications in therapies for severe anti-fungal infections and multi-drug resistant infectious diseases. The Aquarius drug delivery platform is based on its proprietary cochleate delivery technology, which is exclusively licensed from Rutgers University (as a successor in interest to the University of Medicine and Dentistry of New Jersey). Aquarius' lead product candidate is an application of cochleate delivery technology to a broad spectrum anti-fungal drug called amphotericin B, for which a single-dose Phase 1 study has been completed.

The merger contemplated by the Merger Agreement (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.

At the effective time of the Aquarius Merger, each issued and outstanding share of Aquarius' common stock (including each share of Aquarius' common stock underlying outstanding convertible notes, which shares were deemed issued and outstanding at the effective time) was converted into and the right to receive an amount, without interest, equal to the per share merger consideration, which is the sum of the per share closing consideration and the per share milestone consideration, and each share of Aquarius' common stock held in treasury was cancelled and extinguished without any payment or distribution. 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. The number of Closing Shares may be adjusted after the closing under the terms of the Merger Agreement but in no event shall the number of Closing Shares exceed 5,000,000 shares of our Common Stock. 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 of the effective time of the Aquarius Merger, following the issuance of the Closing Shares, the former Aquarius stockholders collectively own approximately 8% of the aggregate number of shares of the Common Stock outstanding (on a fully diluted basis), and the stockholders of Matinas as of immediately prior to the Aquarius Merger (the "Company Stockholders") own approximately 92% of the aggregate number of shares of the Common Stock outstanding (on a fully diluted basis). These percentage figures do not take into account the potential issuance of the Additional Shares or the potential effect of indemnification claims.

Under certain limited 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 Company's 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 commercially reasonable efforts to obtain.

The foregoing descriptions of the Merger Agreement and Aquarius Merger are not complete and are qualified in their entirety by reference to the Merger Agreement, which is included as Exhibit 2.1 to our Form 8-K filed with the SEC on January 30, 2015 and incorporated herein by reference.

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.

BDSI terminated its relationship with Dr. Mannino in September 2009 and subsequently decided to discontinue its development efforts with respect to the cochleate delivery technology. In June 2012, BDSI entered into an agreement to terminate its license agreement with Rutgers, The State University of New Jersey (successor in interest to the University of Medicine and Dentistry of New Jersey) and certain sublicenses related to the cochleate delivery technology. Pursuant to this agreement, BDSI assigned to Rutgers its know-how and patent rights to the cochleate delivery technology in consideration of 10% of future potential revenues collected by Rutgers following commercialization of the formulated amphotericin B products (now MAT2203) and 3.5% for non- cochleate formulated amphotericin B products, which utilize such patent rights and know-how.

Aquarius Biotechnologies Inc. was founded and formed in June of 2012 as a Delaware corporation, with Dr. Raphael Mannino as its key founding shareholder. From June of 2012 and March of 2013 Aquarius discussed and negotiated the terms of a license agreement with Rutgers, The State University of New Jersey following Rutgers having obtained all rights to the patents and know-how back from BDSI. Aquarius and Rutgers entered into a license agreement, dated March 25, 2013 granting Aquarius the exclusive rights to develop and commercialize the cochleate delivery technology worldwide. Thereafter, in August of 2014, Aquarius acquired Coordinated Program Development, LLC, where Dr. Susan Bonitz had been working on cochleate delivery technology independently. Dr. Bonitz joined Aquarius as its Senior Vice President of Business Development and Aquarius continued to develop the cochleate delivery technology until its acquisition by Matinas in January 2015.

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. Aquarius 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 17 issued and foreign patents, including 10 patents issued within the last 3 years, which extends patent protection until at least 2027. 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.

Matinas-Owned Intellectual Property Relating to MAT9001 and MAT8800

We have sought patent protection in the United States and internationally for MAT9001 and our MAT8800 discovery program, and any other inventions to which we have rights, where available and when appropriate. Our policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business.

Our current patent portfolio relating to MAT9001 and MAT8800 is comprised of one patent issued in December 2014 which covers, amongst other claims, the use of docosapentaenoic acid (DPA) for the reduction of triglycerides. This patent provides important protection to MAT9001 through 2033. In addition, we have nineteen additional patent applications across four patent families covering the oil composition for MAT9001 and potential compositions under evaluation in our MAT8800 discovery program, other omega-3 fatty acid compositions, as well as formulations of MAT9001 and similar formulations. All of these filed patent applications also comprise methods of use of such oil compositions and formulations. Any patents that may issue from these filed United States patent applications and their counterpart international application covering the MAT9001 drug substance, formulation, and methods for use in treatment would extend protection until at least 2033.

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. 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 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
- Gilead, the manufacturer of AmBisome B (liposomal amphotericin B), as well as the generic manufacturer of amphotericin B.

In addition, Astellas Pharmaceuticals and Basilea Pharmaceuticals recently announced that FDA approved Astellas' New Drug Application (NDA) for the use of isavuconazole for patients 18 years of age and older in the treatment of invasive aspergillosis and invasive mucormycosis (also known as zygomycosis). These are life-threatening fungal infections predominantly occurring in immunocompromised patients. Basilea's partner Astellas will market the drug as CRESEMBA® (isavuconazonium sulfate) in the United States.

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 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, plazomycin, which is being developed by Achaogen, Inc.; eravacycline, which is being developed by Tetraphase Pharmaceuticals, Inc.; and Brilacidin®, being developed as a broad spectrum anti-bacterial by Cellceutix Corporation.

Competition for MAT9001

We are positioning MAT9001 to gain approval in the hypertriglyceridemia market with an initial indication to treat patients with severe hypertriglyceridemia, which is characterized by triglyceride levels at >500 mg/dL. The current market for hypertriglyceridemia treatments is dominated by three therapeutic classes: fibrates, extended release niacin, and omega-3 fatty acid based products. We believe that our key competitors for treatment of severe hypertriglyceridemia are:

- Abbvie, Inc. (previously Abbott Laboratories), which currently markets Tricor® and Trilipix® (both fibrates) and Niaspan® (niacin) in the United States and Omacor (the equivalent of Lovaza) in Europe and Asia;
- GlaxoSmithKline plc, which currently markets Lovaza, a prescription omega-3 fatty acid in the United States;
- several local, European or global pharmaceutical companies, which market Omacor, Zodin and Seacor (all essentially equivalents of Lovaza) in Europe;
- Amarin, which recently launched Vascepa, an ethyl-ester form of EPA;
- Mochida, which has been selling Epadel, an ethyl-ester form of EPA, in Japan, and Takeda Pharmaceutical Company Limited, which recently received approval of its version of Omacor in Japan; and
- Apotex Inc., Teva Pharmaceuticals USA, Inc., and Par Pharmaceutical Inc., each of which are selling or pursuing generic versions of Lovaza/Omacor.

In addition, we are aware of other companies that are developing omega-3 products, which we believe, if approved and marketed, will compete directly with MAT9001, including Omthera Pharmaceuticals, now owned by AstraZeneca PLC, Acasti Pharma Inc., a subsidiary of Neptune Technologies and Bioresources Inc., Catabasis Pharmaceuticals, or Catabasis, Resolvyx Pharmaceuticals, or Resolvyx, and Sancilio & Company and Trygg Pharma AS. Furthermore, MAT9001, along with currently-marketed prescription-only omega-3 products, may also compete with a multitude of omega-3 dietary supplements that are available over-the-counter without a prescription.

Competition for MAT8800

Our MAT8800 discovery program is seeking to identify and develop product candidates derived from omega-3 fatty acids for the treatment of prevalent liver diseases for which there are currently only limited therapeutic solutions. This discovery program is focused on identifying and optimizing product candidates comprising omega-3 fatty acids as potential treatments for nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH) or other hepatic conditions. There are currently no therapeutic products approved for the treatment of NASH or NAFLD.

There are several marketed therapeutics that are currently used off label for the treatment of NASH, such as insulin sensitizers (e.g., metformin), antihyperlipidemic agents (e.g., gemfibrozil, pioglitazone), pentoxifylline and ursodiol, but none has been clearly shown in clinical trials to alter the course of the disease. We are aware of several companies that have product candidates in Phase 2 clinical development or earlier preclinical development for the treatment of NASH, including Intercept Pharmaceuticals, Inc., Gilead Sciences, Inc., Dr. Falk Pharma GmbH, Galmed Medical Research Ltd., Immuron Ltd., Mochida Pharmaceutical Co., Ltd., NasVax Ltd. and Raptor Pharmaceutical Corp., and there are other companies with candidates in earlier stage programs.

Many of our competitors and potential competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to our programs or advantageous to our business.

Manufacturing

We do not currently own or operate sufficient manufacturing facilities for the production of clinical or commercial quantities of any of our other product candidates. To date, we have only developed limited in-house manufacturing capabilities for MAT9001 and for cochleates needed for our MAT2203 and MAT2501 product candidates. We currently contract with one third party manufacturer to supply us with MAT9001 intermediate drug substance and a second manufacturer to provide MAT9001 capsules. If any of these manufacturers should become unavailable to us for any reason, we have identified a number of potential replacements, although we might incur some delay in qualifying such replacements. 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 be dependent on a small number of third-party manufacturers for the manufacture of our product candidates. If any of our products are approved by any regulatory agency, we intend to enter agreements with third-party contract manufacturers for the commercial production of those products.

There are a number of potential third party suppliers for amphotericin B and amikacin. 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.

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.

Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval for new or improved formulations of previously approved products, a company may file a Section 505(b)(2) NDA. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The Hatch-Waxman Amendments permit the applicant to rely upon certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, which is referred to as the Reference Listed Drug, the applicant is required to certify to the FDA concerning any listed patents in the FDA's Orange Book publication that relate to the Reference Listed Drug. Specifically, the applicant must certify for all listed patents one of the following certifications: (i) the required patent information has not been filed by the original applicant; (ii) the listed patent already has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product.

If a Paragraph I or II certification is filed, FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. If an application contains a Paragraph IV certification, a series of events will be triggered, the outcome of which will determine the effective date of approval of the 505(b)(2) application. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the Referenced Listed Drug has expired.

A certification that the new product will not infringe the Reference Listed Drug's listed patents or that such patents are invalid is called a Paragraph IV certification. If the 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 for the Reference Listed Drug once the applicant's NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA by imposing a 30 month automatic statutory injunction. The court may shorten or lengthen the 30 month stay period in a pending patent case if either party fails to reasonably cooperate in expediting the case. The 30 month stay terminates if a court issues a final order determining that the patent is invalid unenforceable or not infringed. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay.

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 $2.1 million, and the sponsor of an approved NDA is also subject to annual product and establishment user fees, currently exceeding $104,000 per product and $554,000 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. *Cryptococcus* species were recently added by the FDA to the list of qualifying pathogens under the GAIN Act. 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 15, 2015, we had 9 full-time employees.

Research and Development

For the years ended December 31, 2013 and December 31, 2014, we spent approximately $1.8 million and $5.2 million, respectively, on research and development activities. These expenses include cash and non-cash expenses relating to the development of our clinical and pre-clinical programs, primarily to support our MAT9001 program.

Formation

In May 2013, Holdings was formed solely to prepare for the capital raising transaction described below under "2013 Private Placement". As part of the formation of Holdings, Holdings sold an aggregate of 7,500,000 shares of Holdings' common stock and 3,750,000 warrants to purchase 3,750,000 shares of its 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 its common stock to Adam Stern and entities owned by Mr. Stern. Mr. Stern is an affiliate of Aegis Capital Corp., the placement agent in Holdings' private placement in 2013 described below under 2013 Private Placement and a member of the board of directors of Holdings. The net cash proceeds of $375,000 has been reflected in the total equity for Holdings. The remaining 5,500,000 shares of its common stock and 2,250,000 warrants to purchase 2,250,000 shares of its common stock were sold to third parties, including certain representatives of Aegis Capital Corp., the placement agent for the 2013 Private Placement.

The aggregate proceeds of the units sold ($375,000 gross proceeds) were allocated between the warrants and the common stock based on their relative fair values which amounted to approximately $300,000 allocated to the common stock and $75,000 allocated to the warrants.

In addition, Holdings also offered and sold to Mr. Stern 250,000 warrants to purchase an additional 250,000 shares of its common stock at an exercise price of $2.00 per share, for which he paid $10,000 (at a purchase price of $0.04 per warrant) (the "Formation Warrants") for his effort in connection with the transaction. These additional Formation Warrants offered to Mr. Stern are compensatory for his services in connection with structuring the formation transaction and were sold at a lower price than the fair value of $0.47 per warrant. The difference of the fair value of the warrants and the cash proceeds in the amount of $108,316 was recorded as acquisition costs incurred in connection with this transaction, and included in general and administrative expenses. Mr. Stern is an affiliate of Aegis Capital Corp., the placement agent in the 2013 Private Placement (the "Placement Agent"), and became a director of Holdings in connection with the transactions described below.

2013 Merger

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 (approximately 28.5% of the issued common shares) of Holdings' 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"). As a result of this 2013 Merger, the shareholders of Matinas BioPharma became shareholders of ours, and the respective holdings of management are as follows: Herbert Conrad, Chairman of the Board, who received 351,563 shares of our common stock and 250,000 Merger Warrants; Roelof Rongen, President and Chief Executive Officer, who received 3,417,186 shares of our common stock, Abdel A. Fawzy, Executive Vice President, Pharmaceutical Development and Supply Chain Development, who received 1,708,593 shares of our common stock; George Bobotas, 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, Executive Vice President, Chief Business Officer and General Counsel, who received 759,374 shares of our common stock and Stefano Ferrari, a member of the board of directors, through an entity controlled by him, received 351,563 shares of our common stock and 250,000 Merger Warrants.

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).

2013 Private Placement

In July and August 2013, we completed 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 (the "Investor Warrants"). The aggregate gross proceeds of the units sold ($15.0 million gross proceeds) were allocated between the warrants and the common stock based on their relative fair values which amounted to approximately $11,983,000 allocated to the common stock and $3,017,000 allocated to the warrants. One of the units was sold to Mr. Herbert Conrad for the full offering price of $250,000, and consisted of 250,000 shares of common stock and 125,000 warrants.

Aegis Capital Corp. acted as the Placement Agent for the 2013 Private Placement. The gross proceeds to us from the 2013 Private Placement were $15.0 million. In connection with the 2013 Private Placement, the Placement Agent received a cash placement agent fee of $1.5 million and a non-accountable expense allowance of $450,000. 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 its 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 its common stock with an exercise price of $1.00 per share. These warrants contain a "cashless exercise" feature and are exercisable at any time prior to July 30, 2018. The fair value of such warrants at the date of issuance was approximately $1.3 million using assumptions similar to those described in Note G and was recorded as part of equity, together with the other sales of common stock and warrants and not as a separate entry in the statement of stockholders equity for this stock issuance cost.

In connection with the closing of the 2013 Private Placement, the Placement Agent had a right to appoint one out of five members of our Board of Directors for a two-year term from the initial closing (the "Aegis Nominee"). Adam Stern was appointed to our Board of Directors at the initial closing and his successor, if any, will be chosen by the Placement Agent, subject to our reasonable approval and the Voting Agreement herein. We agreed to engage the Placement Agent as its warrant solicitation agent in the event the warrants, other than the Placement Agent 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.

After the consummation of the 2013 Merger and the 2013 Private Placement, the former shareholders of Matinas BioPharma held 28.5% of the common stock of Holdings by category of these transactions and approximately 30% when the additional shares purchased by Mr. Conrad in the 2013 Private Placement are included.

The private placement issuance cost totaled approximately $2.4 million of which $1.95 million was related to Placement Agent cash fees and expenses, $425,000 related to external legal costs and the remaining balance in other costs directly and incrementally attributable to the private placement funds raised. These costs are reflected as an offset to additional paid in capital.

Warrant Private Placement

Contemporaneously with the initial closing of the 2013 Private Placement, we offered to all former preferred stockholders of Matinas BioPharma the right to purchase additional warrants with an exercise price of $2.00 per share of our common stock at a purchase price of $0.04 per warrant. Only Mr. Conrad exercised such right. As a result, we sold 500,000 Private Placement Warrants to Herbert Conrad, our Chairman of the Board, for net cash proceeds of $20,000.

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. 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 079219, 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 $10.2 million and $3.7 million for the years ended December 31, 2014 and 2013, respectively. As of December 31 2014, we had an accumulated deficit of $14.1 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 our members' deficit and working capital. 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 MAT9001, MAT2501 and MAT8800;
- 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, 2014 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, but this product candidate cannot be marketed for any indication until regulatory approvals have been obtained. In addition, as a result of our acquisition of Aquarius Biotechnologies, Inc. in January 2015, we acquired our lead anti-infective product candidate, MAT 2203, as well as 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 initiate the planned Phase 2a clinical trial of MAT2203, advance MAT9001 in its planned development programs and also 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 $2.6 million as of December 31, 2014, will enable us to fund our operating expenses and capital expenditure requirements through April 2015. 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 and a possible Phase 3 clinical trial of MAT9001;

- the scope, progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for, other product candidates, including MAT2501 and a product candidate which emerges from our MAT8800 discovery program, 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 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 our operations to date have been limited to organizing and staffing the company, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies and, beginning in 2014, conducting clinical trials. All but two of our product candidates are still in preclinical development. We have not yet demonstrated our ability to successfully obtain regulatory approvals, 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. 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 Aquarius Acquisition

Our business combination with Aquarius Biotechnologies is expected to result in benefits to the combined Company, but the combined Company may not realize those benefits due to challenges associated with integrating the companies or other factors.

We have recently completed a business combination with Aquarius. The success of the business combination will depend in part on the success of our management in integrating the operations, technologies, product candidates and clinical programs of the two companies. The inability of the combined Company to meet the challenges involved in integrating successfully our operations, in developing the technologies and product candidates acquired from Aquarius Biotechnologies or to otherwise realize any of the anticipated benefits of the business combination could seriously harm the combined Company's results of operations. In addition, the overall integration of the two companies may result in unanticipated operations problems, expenses, liabilities and diversion of management's attention. The challenges involved in integration include:

- integrating the two Company's operations, technologies, clinical programs and product candidates;
- coordinating and integrating research and development activities;
- continuing to develop the technologies and product candidates acquired from Aquarius Biotechnologies;
- consolidating corporate and administrative infrastructures and eliminating duplicative operations; and
- maintaining employee morale and motivation.

We may not be able to successfully integrate our operations in a timely manner, or at all, and the combined Company may not realize the anticipated benefits of the business combination, including synergies or growth opportunities, to the extent or in the time frame anticipated. The anticipated benefits and synergies of the business combination are based on assumptions and current expectations, not actual experience, and assume a successful integration. In addition to the potential integration challenges discussed above, the combined Company's ability to realize the benefits and synergies of the business combination could be adversely impacted to the extent that our relationships with existing or potential customers, suppliers or strategic partners is adversely affected as a consequence of the business combination, or by practical or legal constraints on its ability to combine operations. Furthermore, financial projections based on these assumptions relating to integration may not be correct if the underlying assumptions prove to be incorrect.

If we discontinue development of the cochleate delivery technology, we would be required to return such technology to the former stockholders of Aquarius and would not realize the anticipated benefits of our business combination with Aquarius.

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. As a result, we would not realize the anticipated benefits of our business combination with Aquarius.

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

Following our acquisition of Aquarius, 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, MAT9001 or any of our other product candidates 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 MAT2203 or any of our other product candidates will materially or adversely harm our business.

To date, we have invested a significant portion of our efforts and financial resources in the development of MAT9001. Following our acquisition of Aquarius, we expect to invest a significant portion 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 MAT2203, MAT2501 or any of our other 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, in large part, 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 planned 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 planned 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.

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 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 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 MAT9001 and for cochleates needed for our MAT2203 and MAT2501 product candidates. If we do not develop an in-house manufacturing capability for MAT9001 and 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 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, 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, MAT9001 or any of our other product candidates, 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 MAT9001, MAT2203 or any of our other product candidates will depend upon its acceptance by the medical community, including physicians, patients and health care payors. The degree of market acceptance of MAT9001, MAT2203 or such other product candidate will depend on a number of factors, including:

- demonstration of clinical safety and efficacy of such product candidate;
- relative convenience, pill burden 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, MAT9001, or any of our other product candidates, 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.

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, MAT9001 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, MAT9001 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, MAT9001 or any of our other product candidates, 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, MAT9001 or any of our other product candidates 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, MAT9001 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 Merck & Co., Tetraphase Pharmaceuticals, Inc., Insmed Incorporated, Achaogen, Inc., and The Medicines Company. With respect to MAT9001, current competitors include GlaxoSmithKline plc, which currently markets Lovaza, a prescription omega-3 fatty acid indicated for patients with severe hypertriglyceridemia; Teva Pharmaceuticals USA, Inc., which currently markets a generic version of Lovaza; Abbvie, Inc. (previously Abbott Laboratories), which currently markets Tricor® and Trilipix® (both fibrates) and Niaspan® (niacin) for the treatment of high triglycerides and severe hypertriglyceridemia in the United States and Omacor (the equivalent of Lovaza) in Europe and Asia; and Amarin Corp. plc, which currently markets Vascepa®, an ethyl-ester form of EPA, for the treatment of patients with severe hypertriglyceridemia and is seeking FDA approval of Vascepa for the treatment of patients with high triglyceride levels (TG ≥200 mg/dL and <500 mg/dL) who are also on statin therapy for elevated LDL-C levels, which has been referred to as Amarin's ANCHOR indication. In addition, we are aware of other companies that are developing products that we believe, if approved and marketed, will compete directly with MAT9001, including Omthera Pharmaceuticals, Inc., now owned by AstraZeneca PLC; Acasti Pharma Inc., a subsidiary of Neptune Technologies and Bioresources Inc.; Catabasis Pharmaceuticals, Inc.; Resolvyx Pharmaceuticals, Inc.; Sancilio & Company, Inc.; and Trygg Pharma AS.

MAT9001 is designed to be a prescription-only omega-3 fatty acid based medication. Omega-3 fatty acid based products are also marketed by other companies as dietary supplements, which, unlike drugs, are not subject to FDA approval and therefore do not require a prescription and are not subject to pharmaceutical manufacturing standards. As a result, MAT9001, if approved, would be subject to competition from products for which no prescription is required.

If approved by the regulatory authorities, MAT9001 will be a prescription-only omega-3 fatty acid based medication. Mixtures of omega-3 fatty acids are naturally occurring substances in various foods, including fatty fish. Omega-3 fatty acids are also marketed as dietary supplements, which may generally be marketed without a lengthy FDA premarket review and approval process and are not subject to prescription. However, unlike prescription drug products, manufacturers of dietary supplements may not make therapeutic claims for their products; dietary supplements may be marketed with claims describing how the product affects the structure or function of the body without premarket approval, but may not expressly or implicitly represent that the dietary supplement will diagnose, cure, mitigate, treat, or prevent disease. We believe the exact omega-3 fatty acid composition and pharmaceutical-grade purity of MAT9001 has a superior therapeutic profile to the omega-3 compositions in commercially available dietary supplements. However, we cannot be sure that physicians or consumers will view MAT9001 as superior. To the extent the price of MAT9001 is significantly higher than the prices of commercially available omega-3 fatty acids marketed by other companies as dietary supplements, physicians may recommend these commercial alternatives instead of MAT9001 or patients may elect on their own to take commercially available non-prescription omega-3 fatty acids. Either of these outcomes may adversely impact our results of operations by limiting product sales and how we price our product, thereby limiting the revenue we receive from sales of MAT9001.

Even if we obtain marketing approval for MAT2203, MAT9001 or any of our other product candidates, 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, MAT9001 or any of our other product candidates, 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 new 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, MAT9001 or any of our other product candidates 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 new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new 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.

Despite initiatives to invalidate the Health Care Reform Law, the United States Supreme Court has upheld certain key aspects of the legislation, including the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the individual mandate. Although there are legal challenges to the Health Care Reform Law in lower courts on other grounds, at this time it appears the implementation of the Health Care Reform Law will continue. We will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Health Care Reform Law, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

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, MAT9001 or any of our other product candidates 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.

The import of our fish oils containing omega-3 fatty acids and concentrates thereof is subject to supervision and licensing by the United States Department of Agriculture.

The import of our fish oils containing Omega-3 fatty acids and concentrates thereof is subject to supervision and licensing by the United States Department of Agriculture ("USDA"). If the USDA were to halt the import of such materials or issuance of licenses for the import of such materials, the development, production, or sale of MAT9001 could be delayed.

We are, and will be, completely dependent on third parties to manufacture MAT9001, and our commercialization of MAT9001 could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of MAT9001 or fail to do so at acceptable quality levels or prices.

We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the active pharmaceutical ingredient, or API, in MAT9001 for use in our clinical trials or for commercial product, if any. In addition, we do not have the capability to encapsulate MAT9001 as a finished drug product for commercial distribution. As a result, we will rely on contract manufacturers throughout the development process and then if and when MAT9001 is approved for commercialization. We have not entered into any agreement with any contract manufacturers for commercial supply and may not be able to engage a contract manufacturer for commercial supply of MAT9001 on favorable terms to us, or at all.

The facilities used by our contract manufacturers to manufacture MAT9001 must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs for manufacture of both active drug substances and finished drug products. These cGMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to MAT9001. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of MAT9001 or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market MAT9001, if approved.

Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with cGMPs and similar regulatory requirements. We do not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market MAT9001, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market MAT9001.

If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished MAT9001 product or should cease doing business with us, we could experience significant interruptions in the supply of MAT9001 or may not be able to create a supply of MAT9001 at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of MAT9001 might be negatively affected. Our inability to coordinate the efforts of our third party manufacturing partners, or the lack of capacity available at our third party manufacturing partners, could impair our ability to supply MAT9001 at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of MAT9001 if we decided to transfer the manufacture of MAT9001 to one or more alternative manufacturers in an effort to deal with the difficulties.

Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a future contract manufacturer caused by problems at suppliers could delay shipment of MAT9001, increase our cost of goods sold and result in lost sales.

We cannot guarantee that our manufacturing and supply partners will be able to reduce the costs of commercial scale manufacturing of MAT9001 over time. If the commercial-scale manufacturing costs of MAT9001 are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time.

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, MAT9001 or any of our other product candidates and our business could be substantially harmed.

We expect to enter into agreements with third-party CROs to conduct and manage our clinical programs. We would rely heavily on these parties for execution of clinical studies for MAT2203, MAT9001 and our other product candidates and would control only certain 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 CROs would not relieve us of our regulatory responsibilities. We 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 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 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 CROs may not perform all of their obligations under their arrangements with us or in compliance with regulatory requirements. If the CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of MAT2203, MAT9001 or any of our other product candidates 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, MAT9001 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, MAT9001 or any of our other product candidates. 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, MAT9001 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, MAT9001 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, MAT9001 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.

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 only one issued patent for MAT9001 and seventeen issued patents relating to our cochleate delivery technology, as well as pending patent applications for MAT9001, the MAT8800 discovery program, and 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. For example, others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to MAT9001, or otherwise important to our business. 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, MAT9001 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, MAT2501, MAT9001, 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, MAT2501, or MAT9001 from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to MAT2203, MAT2501 or MAT9001 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, MAT9001 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, MAT9001 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.

A number of companies and research institutions, including several major pharmaceutical companies, have conducted research on pharmaceutical uses of omega-3 fatty acids, which has resulted in the filing of many patent applications related to this research. We are aware of third-party United States patents/applications, and corresponding foreign counterparts, that contain broad claims related to methods of using these general types of compounds, which may be construed to include potential uses of MAT9001 or any future product candidates. If we were to challenge the validity of these or any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every issued United States patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. If we were to challenge the validity of these or any issued United States patent in an administrative trial before the Patent Trial and Appeal Board in the United States Patent and Trademark Office, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and/or court would find in our favor on questions of infringement, validity or enforceability.

Our intended path for FDA approval of MAT9001 with an indication to treat severe hypertriglyceridemia involves the filing of a Section 505(b)(2) NDA. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit us to rely upon certain preclinical or clinical studies conducted by third parties for their approved product. As a result, we are allowed under Section 505(b)(2) to file an NDA utilizing information from these studies even though we have not obtained a right of reference The FDA may require us to perform additional studies or measurements to support any changes in our product as compared to the approved product. Pursuant to an NDA filed under Section 505(b)(2), the FDA may approve our new product for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by us.

If a Paragraph I or II certification is filed, FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. If an application contains a Paragraph IV certification, a series of events will be triggered, the outcome of which will determine the effective date of approval of the 505(b)(2) application. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the Referenced Listed Drug has expired.

A certification that the new product will not infringe the Reference Listed Drug's listed patents or that such patents are invalid is called a Paragraph IV certification. If the 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 for the Reference Listed Drug once the applicant's NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a Paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA by imposing a 30 month automatic statutory injunction. The court may shorten or lengthen the 30 month stay period in a pending patent case if either party fails to reasonably cooperate in expediting the case. The 30 month stay terminates if a court issues a final order determining that the patent is invalid unenforceable or not infringed. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the applicant's NDA will not be subject to the 30-month stay.

If MAT9001 is not granted any exclusivity protection from the FDA our business may be materially harmed.

Under Sections 505(c)(3)(E)(ii) and 505(j)(5)(F)(ii) of the Food Drug and Cosmetic Act, or FDCA, as amended by the Hatch-Waxman Amendments, a drug that is granted regulatory approval may be eligible for five years of marketing exclusivity in the United States following regulatory approval if that drug is classified as a new chemical entity, or NCE. A drug can be classified as a NCE if the FDA has not previously approved any other drug containing the same active moiety.

The FDA typically publishes a determination on the marketing exclusivity of recently approved products in a cumulative supplement to its Approved Drug Products with Therapeutic Equivalence Evaluations , also known as the Orange Book, mid-month in the month following the drug's approval. NCE marketing exclusivity, if granted, would preclude approval during the five-year exclusivity period of certain 505(b)(2) applications or certain abbreviated new drug applications submitted by another company for another version of the drug. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. If we are not able to gain or exploit the period of marketing exclusivity, we may face significant competitive threats to our commercialization of these compounds from other manufacturers, including the manufacturers of generic alternatives. Further, even if MAT9001 is considered to be a NCE and we are able to gain five-year marketing exclusivity, another company could challenge that decision to seek to overturn the FDA's determination. Another company could also gain such marketing exclusivity under the provisions of the FDCA, as amended by the Hatch-Waxman Amendments, if such company can, under certain circumstances, complete a human clinical trial process and obtain regulatory approval of its product.

If MAT9001 is not granted NCE marketing exclusivity, we expect it will be granted three years of new product exclusivity under the Hatch-Waxman Amendments. Such exclusivity protection would preclude the FDA from approving a marketing application for a duplicate of MAT9001, a product candidate that the FDA views as having the same conditions of approval as MAT9001 (for example, the same indication and/or other conditions of use), or a 505(b)(2) NDA submitted to the FDA with MAT9001 as the reference product, for a period of three years from the date of FDA approval, although the FDA may accept and commence review of such applications during the exclusivity period. Such three-year exclusivity grant would not prevent a company from challenging the validity of our patents at any time. In this case, we may be afforded the benefit of a 30-month stay against the launch of such a competitive product that would extend from the period that we respond to a pending patent challenge. This three-year form of exclusivity may also not prevent the FDA from approving an NDA that relies only on its own data to support the change or innovation.

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

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

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

We may seek orphan drug designation for MAT-2203 in the United States and may seek 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 may seek fast track designation for some of our product candidates or priority review of applications for approval of our product candidates. 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 also be granted priority review by the FDA and can 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 that is 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 nine 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 Chief Business Officer and General Counsel, would adversely impact our business prospects.

Our ability to compete in the highly competitive pharmaceuticals 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, MAT9001 or any of our other product candidates and will face an even greater risk if we commercialize MAT2203, MAT9001 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 MAT9001. 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, MAT9001 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 intend to obtain product liability insurance covering our clinical trials in the amount of greater than or equal to $1 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”. However, prior to July 21, 2014, there was no trading activity in our Common Stock and limited trading has occurred 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 July 21, 2014 through March 20, 2015, the market price of our Common Stock has fluctuated from a high of $1.35 per share to a low of $0.31 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 will incur 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 will incur 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. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. We are just beginning the process of compiling the system and processing documentation needed to comply with such requirements. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. In that regard, we currently do not have an internal audit function, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

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

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

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

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 transition to operating as a public company, 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, even if established, 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.

We may be unable to complete our analysis of our internal controls over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our Company and, as a result, the value of our Common Stock.

Beginning with our annual report for the fiscal ended December 31, 2015, our management, including our principal executive officer and principal financial officer, will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting, as well as a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting.

We are in the very early stages of the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective.

If we are unable to assert that our internal control over financial reporting is effective, or, if applicable, our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, we could lose investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our Common Stock to decline, and we may be subject to investigation or sanctions by the SEC. We will also be required to disclose changes made in our internal controls and procedures on a quarterly basis.

However, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC, or the date we are no longer an "emerging growth company" as defined in the recently enacted JOBS Act, if we take advantage (as we expect to do) of the exemptions contained in the JOBS Act.

At such time that we no longer qualify as an emerging growth company, our independent registered public accounting firm may issue a report that is adverse to us in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in our internal control over financial reporting in the future. Any of the foregoing occurrences, should they come to pass, could negatively impact the public perception of our company, which could have a negative impact on our stock price.

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 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.

Holders

As of March 20, 2015, we had approximately 215 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, 2014.

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 related financing, 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

On January 29, 2015, we completed the acquisition of Aquarius Biotechnologies Inc., (referred to as the "Aquarius Merger" throughout this document and which is discussed in more detail under the section titled "Recent Developments" in "Item 1. Business"), 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 the development of targeted therapeutics using our innovative lipid-based drug delivery platform with an initial focus on the treatment of serious fungal and bacterial infections and the development of lipid-based prescription therapeutics for the treatment of cardiovascular and metabolic conditions.

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. 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.

Our lead product candidate for the treatment of infectious diseases is MAT 2203, an oral formulation of a broad spectrum anti-fungal drug called amphotericin B using our acquired cochleate delivery technology, for which a single-dose Phase 1a study has been completed. We expect to commence and complete 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, in 2015, with results expected in the fourth quarter of 2015. We are developing a pipeline of oral products by applying our cochleate delivery technology to a potentially broad array of established pharmaceuticals, including MAT 2501, an application of our cochleate delivery technology to a 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. We also continue to focus on identifying and developing novel pharmaceutical lipid-based products, including MAT9001 with an initial indication for the treatment of highly elevated triglycerides, or severe hypertriglyceridemia. Finally, our MAT8800 discovery program is seeking to identify and develop product candidates derived from omega-3 fatty acids for the treatment of non-alcoholic fatty liver disease for which there are currently no therapeutic solutions available.

We are a development stage company and have not generated any revenues. We have never been profitable. Our net loss was approximately $10.2 million and $3.7 million for the fiscal years ended December 31, 2014 and 2013, 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, MAT2501, MAT9001 and our other product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company, including compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. 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. We will need to generate significant revenues to achieve profitability, and we may never do so.

Acquisition of Aquarius Biotechnologies

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 Merger Agreement (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. The number of Closing Shares may be adjusted after the closing under the terms of the Merger Agreement but in no event shall the number of Closing Shares exceed 5,000,000 shares of our Common Stock. 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.

Additional (one time) liabilities of approximately $ 400,000 were incurred to complete the transaction and we expect that for the remainder of 2015 that the transaction will have a minimal impact on our liquidity.

Financial Operations Overview

Revenue

To date, we have not generated any revenue. Our ability to generate product revenue from our legacy products, which we do not expect to occur before 2018, if ever, will depend significantly on the successful development and eventual commercialization of MAT9001. We will generate contract revenue resulting from the acquisition of Aquarius.

Research and Development Expenses

Research and development expenses consist of costs incurred for the development of MAT9001 and identification of product candidates under our MAT8800 discovery program, which include:

- the cost of conducting pre-clinical work;
- the cost of acquiring, developing and manufacturing pre-clinical trial materials;
- costs for consultants and contractors associated with Chemistry and Manufacturing Controls (CMC), pre-clinical activities and regulatory operations;
- expenses incurred under agreements with contract research organizations, or CROs, that conduct our pre-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 MAT9001 for the years ended December 31, 2014 and 2013. Our direct research and development expenses consist principally of external costs, such as fees paid to contractors, consultants, analytical laboratories and CROs, in connection with our development work. We typically use our employee and infrastructure resources for developing MAT9001.

	Year Ended December 31,	
	2014	**2013**
	($ in thousands)	
Direct research and development expenses:		
Manufacturing process development	$ 1,373	$ 654
Preclinical trails	299	236
Clinical Development	955	0
Regulatory	413	113
Internal staffing, Overhead and Other	2,134	758
Total research & development	$ 5,175	$ 1,761

Research and development activities are central to our business model. 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.

We believe we have optimized the manufacturing process for the active pharmaceutical ingredient of MAT9001 and have completed various preclinical studies with the MAT9001 active ingredient. We completed the first preclinical studies of MAT9001 during the fourth quarter of 2013 with others completed during 2014. We commenced manufacturing of GMP batches of MAT9001 late in the first quarter of 2014. We filed our IND for MAT9001 with the FDA on October 20, 2014 and obtained approval on December 1, 2014. We started the first human study of MAT9001 during the fourth quarter of 2014. As noted above, on January 29, 2015 we acquired Aquarius. With this acquisition, we will be moving forward on developing the product candidates and technology we acquired from Aquarius, including MAT2203 and MAT2501.

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, communication expenses, and professional fees for legal, patent review, consulting and accounting services.

We anticipate that our general and administrative expenses will increase in 2015 due to many factors, the most significant of which include:

- increased staff personnel as we expand our operations to prepare for and execute upon our research and development programs; and

- increased expenses related to becoming 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)

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 income/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 Quarterly Report. We believe the following accounting policies 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 MAT9001;
- 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.

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. Determining the amount of share-based compensation to be recorded required us to develop estimates of the fair value of stock options as of their grant date before operating as a public company. 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 privately-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, 2014 and 2013 and to re-measure stock options issued to consultants.

	For the year ended December 31,	
	2014	**2013**
Volatility	68.76%	81.06%
Risk-free interest rate	1.65% - 1.93%	1.85% – 2.15%
Dividend yield	0.0%	0.0%
Expected life	4.75 – 5.5 years	5.0 – 6.0 years

The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding and is based on the options vesting term, contractual terms, and industry peers as we did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.

The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as we did not have any 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 and restricted stock granted to employees and non-employees was $ 2.0 million for 2014 and $ 326,000 for 2013. As of December 31, 2014, 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 2.0 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.

We have included stock based compensation as part of our operating expenses in our statement of operation for the years ended December 31, 2014 and 2013 ($ in thousands) as follows:

	Year ended December 31,	
	2014	2013
General and administrative	$ 1,576	$ 244
Research and development	398	82
Total	$ 1,974	$ 326

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, 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, 2014, there were 2,603,933 shares of our common stock available for issuance under the Plan.

As of December 31, 2014, we had outstanding options to purchase an aggregate of 5,353,417 shares of our common stock with a weighted average exercise price of $1.06. At December 31, 2014, 2,462,569 options had vested at a weighted average exercise price of $1.05 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, 2014. The total intrinsic value of options outstanding and vested at December 31, 2014 was $0.

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, 2014 and 2013.

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, 2014 and 2013

	Year Ended December 31,		Increase
	2014	2013	(Decrease)
	(In thousands)		
Expenses:			
Research and development	$ 5,176	$ 1,761	$ 3,415
General and administrative	5,289	1,951	3,338
Operating Expenses	$ 10,465	$ 3,712	$ 6,753

Research and Development expenses. Research and development expense for the year ended December 31, 2014 was $5.2 million, compared to $1.8 million for the year ended December 31, 2013, an increase of $3.4 million. The increase in research and development expense was primarily due to an increase in activities for the development of the manufacturing process for MAT9001, the costs incurred for clinical studies, increases in stock based compensation, increased headcount and the costs incurred to build out our R&D infrastructure.

General and Administrative expenses. General and administrative expense for the year ended December 31, 2014 was $5.3 million compared to $2.0 million for the year ended December 31, 2013, an increase of $3.3 million. The increase in general and administrative expense was primarily due to increased compensation expenses, particularly associated with share based compensation, new employee compensation, ongoing accounting and legal and professional services, including those legal services associated with intellectual property filings and the registration statement covering the resale of the shares of common stock, as well as increased costs of operating as a public company.

As noted previously, in terms of operating expenses (particularly compensation expenses), 2013 represented a partial year (i.e. start-up year), hence 2014 is showing increased expenses due to a full year of operations in both Research and Development, and General and Administrative expenses.

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, 2014, we have raised a total of $13.5 million in net proceeds from sales of our equity securities.

As of December 31, 2014, we had cash totaling $2.6 million.

2013 Private Placement

In July and August 2013, we completed 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. Aegis Capital Corp. acted as the Placement Agent for the 2013 Private Placement (the "Placement Agent"). The gross proceeds to us from the 2013 Private Placement were $15.0 million.

Warrant Private Placement

Contemporaneously with the initial closing of the 2013 Private Placement, we sold 500,000 Private Placement Warrants 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, and only Mr. Conrad exercised the offer.

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, 2014	
	2014	**2013**
Cash used by operating activities	$ (7,961)	$ (2,988)
Cash used by investing activities	(289)	(94)
Cash provided by financing activities	-	13,498
Net increase/(decrease) in cash and cash equivalents	$ (8,250)	$ 10,416

Operating Activities

We have incurred significant costs in the area of research and development, including manufacturing, analytical, regulatory and other development costs, as the manufacturing process for our product was being developed. Net cash used in operating activities was approximately $8.0 million for the year ended December 31, 2014 and $3.0 million for the year ended December 31, 2013. The increase in cash used in operating activities for the year ended December 31, 2014 compared to the year ended December 31, 2013 was primarily due to higher development costs in connection with development of the manufacturing process, clinical costs, compensation/infrastructure expenses and the costs in connection with fund raising activities and compliance. We expect that there will be a significant increase in cash used in our operating activities during 2015 as we continue to move our product candidates forward in their development cycle.

Investing Activities

Net cash used in investing activities was $289,000 for the year ended December 31, 2014 and $94,000 for the year ended December 31, 2013. The cash used in investing activities for the year ended December 31, 2014 was primarily the purchase of scientific laboratory equipment.

Financing Activities

Net cash provided by financing activities was $0 for the year ended December 31, 2014 and $13.5 million for the year ended December 31, 2013. The cash provided by financing activities for the year ended December 31, 2013 was primarily due to proceeds received from our Private Placement.

Funding Requirements and Other Liquidity Matters

MAT9001, MAT2203 and MAT2501 are still in development stages and our MAT8800 discovery program is in a very early stage. 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 MAT9001 and MAT2501;
- seek to discover and develop additional product candidates, including under our MAT8800 discovery program;
- 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 April 2015. We 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, validate the manufacturing processes at our various suppliers and prepare for submission of an NDA for MAT2203, MAT2501 and MAT9001, and conduct preclinical work in order to identify product candidates under our MAT8800 discovery program. 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.

Until the time we can generate substantial product revenues from commercializing MAT2203, MAT2501, MAT9001 or any of our other 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 $152,000 per year, increasing to $174,000 in the final year.

In December 2014, the Company entered into an agreement to lease laboratory space for one year commencing January 1, 2015 in Monmouth Junction, New Jersey. Base rent for the year ended December 31, 2014 will be approximately $26,000.

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.

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.

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.

RECENT ACCOUNTING PRONOUNCEMENTS

Refer to Note 2, “Significant Accounting Policies,” in the accompanying notes to the condensed consolidated financial statements for a discussion of recent accounting pronouncements.

Item 7A. Quantitative And Qualitative Disclosures About Market Risk

Not applicable.

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, 2014, 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, 2014. 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.

This annual report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting during the three months ended December 31, 2014 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	82	Chairman of the Board, Director
Roelof Rongen	49	President and Chief Executive Officer, Director
Jerome D. Jabbour	40	Executive Vice President Chief Business Officer, General Counsel and Secretary
George Bobotas	67	Executive Vice President and Chief Scientific Officer
Abdel A. Fawzy	64	Executive Vice President, Pharmaceutical Development and Supply Chain
Gary Gaglione	62	Vice President of Finance and Accounting and Acting Chief Financial Officer
Douglas F. Kling	41	Senior Vice President for Clinical Development and Project Management
Stefano Ferrari	54	Director
Adam Stern	50	Director
James S. Scibetta	50	Director

Management

Roelof Rongen has served as our President and Chief Executive Officer and one of our directors since the 2013 Merger 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 has served as our Executive Vice President, Chief Business Officer, General Counsel and Secretary since October 2013 and as one of our directors from the 2013 Merger 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.

George Bobotas, PhD has served as our Executive Vice President and Chief Scientific Officer since the 2013 Merger and as Executive Vice President and Chief Scientific Officer of Matinas BioPharma since August 2011. Dr. Bobotas is a Co-Founder of Matinas BioPharma. Prior to Matinas BioPharma, Dr. Bobotas was a founder of Demelle BioPharma, LLC DeMelle BioPharma, a consulting firm (2008-2012) and Vice President Scientific Affairs at Reliant (2000-2008). Prior to Reliant, he was the founder and Executive Director of the Covance Center for CNS Research (1997-2000). Earlier in his career, Dr. Bobotas held senior positions at Somerset Pharmaceuticals, Inc. (1994-1997), Mylan Laboratories Limited (1988-1994), and Forest Laboratories Inc. (1981-1988). He is the inventor on 22 published patents and patent applications all related to health and pharmaceutical development and manufacturing processes. Dr. Bobotas received his Ph.D. in Biochemistry from the City University of New York, an M.A. in Physical Chemistry from Smith College, Northhampton, Massachusetts, and a B.A. in Chemistry from Windham College, Vermont.

Abdel A. Fawzy, PhD has served as our Executive Vice President for Pharmaceutical and Supply Chain Development since the 2013 Merger 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., responsible for budgeting and planning (2011). In 2009 and 2010, he was Vice President of Finance and Controller for Phytomedics, Inc., a start-up botanical pharmaceutical company. Prior to Phytomedics, he was Controller for ProStrakan Inc.'s U.S. operations (2008-2009). 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), Director of Compensation with responsibility for executive payroll, payroll, benefits, and exempt/non-exempt compensation systems (1995-1997), and Controller for the US pharmaceutical division and sites (1985-1997). 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, Villanova, Pennsylvania, and an MBA in Finance from Seton Hall University, West Orange, New Jersey.

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 the 2013 Merger 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), Tekmira Pharmaceuticals, Inc. (NASDAQ: TKMR) 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 the Merger 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 the first omega-3-based medication. 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 omega-3 based drugs and dietary supplements, 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 following the 2013 Merger. 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 Chief Financial Officer of Pacira Pharmaceuticals, Inc. (NASDAQ: PCRX), a position he has held since August 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.

Scientific Advisory Board

We believe in seeking and attracting scientific and clinical leaders in the field of cardiovascular medicine and their underlying physiology/biology to provide counsel and support our growth. We established two Scientific Advisory Boards 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 Nasdaq'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 – 2014

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

Name and Principal Position [1]	Year	Salary ($)	Bonus ($)	Option Awards(1) ($)	All Other Compensation($)	Total ($)
Roelof Rongen	2014	300,00001	50,000	112,005	—	462,005
President and Chief Executive Officer	2013	27,308(2)	150,000(3)	31,961	1,926(4)	311,195
George Bobotas	2014	250,000	25,000	112,005	-	387,005
Executive Vice President and Chief Scientific Officer	2013	106,090(2)	125,000(3)	31,961	-	263,051
Abdel A. Fawzy	2014	250,000	25,000	112,005	-	387,005
Executive Vice President, Supply Chain Development	2013	106,090(2)	125,000(3)	31,961	-	263,051
Jerome D. Jabbour, *Executive Vice President, Chief Business Officer, General Counsel and Secretary*	2014	275,000	30,000	112,005	-	417,005

(1) Amounts reflect the grant date fair value of option awards granted and vested in 2014 and 2013 in accordance with Accounting Standards Codification Topic 718. These amounts do not correspond to the actual value that will be recognized by the named executive officers.

(2) Each of the named executive officers began receiving salary on July 30, 2013.

(3) Represents signing bonuses paid to each of the named executive officers.

(4) Represents medical insurance premiums paid by us.

Narrative Disclosure to Summary Compensation Table

Employment Agreements with Our Named Executive Officers

On July 30, 2013 and in connection with the Merger, 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.

On July 30, 2013 and in connection with the Merger, we entered into an employment agreement with Mr. Bobotas for a period of three years. Under the terms of Dr. Bobotas' 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. Bobotas 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. Bobotas will also be eligible to receive option grants at the discretion of our Compensation Committee. In October 2013, Mr. Bobotas 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. Bobotas's employment without cause or Dr. Bobotas 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. Bobotas's employment without cause during the 24 month period immediately following a change of control or Dr. Bobotas 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. Bobotas' 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. Bobotas will also be subject to a customary non-disclosure agreement, pursuant to which Mr. Bobotas 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.

On July 30, 2013 and in connection with the Merger, 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.

On September 3, 2013, we entered into an employment agreement with Mr. Jabbour for a period of three years, which will be 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.

Outstanding Equity Awards at Fiscal Year-End Table – 2014

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, 2014.

	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	145,833	204,167	$ 1.28	July 20, 2024
	165,278	184,722	$ 0.94	October 2,2023
George Bobotas	145,833	204,167	$ 1.28	July 20, 2024
	165,278	184,722	$ 0.94	October 2, 2023
Abdel A. Fawzy	145,833	204,167	$ 1.28	July 20, 2024
	165,278	184,722	$ 0.94	October 2,2023
Jerome D. Jabbour	145,833	204,167	$ 1.28	July 20, 2024
	154,167	195,833	$ 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 in connection with the closing of the Merger. 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 aggregate number of shares of common stock available for issuance in connection with awards granted under the 2013 Plan is 8,250,000 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 – 2014

The following table summarizes the annual compensation for our non-employee directors during 2014.

Name	Fees Earned or Paid in Cash ($)	Stock Awards($) (1)	Option Awards ($) (1)	Total ($)
Herbert Conrad	17,500	42,245	58,937	118,682
Stefano Ferrari	12,500	28,008	50,029	90,537
James S. Scibetta	15,000	29,240	50,029	94,269
Adam Stern	10,000	17,510	50,029	77,539

(1) Amounts reflect the grant date fair value of option awards granted in 2014 in accordance with Accounting Standards Codification Topic 718. These amounts do not correspond to the actual value that will be recognized by the directors.

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 1, 2015 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 36,900,670 shares outstanding as of March 1, 2015. 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 1, 2015. 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)	2,850,000	7.5%
Laurence G. Allen(2)	2,111,250	5.6%
Named Executive Officers, Executive Officers and Directors:		
Roelof Rongen(3)	3,724,143	10.0%
Herbert Conrad(4)	1,783,208	4.7%
Stefano Ferrari(5)	842,846	2.3%
James S. Scibetta(6)	196,899	*
Adam Stern (7)	4,659,416	11.8%
George Bobotas, Ph.D. (8)	1,657,162	4.5%
Abdel A. Fawzy, Ph.D.(9)	2,066,937	5.6%
Gary Gaglione(10)	97,778	*
Jerome Jabbour(11)	1,073,966	2.9%
Douglas King(12)	-	-
Directors and Executive Officers as a group (10 persons) (13)	16,102,355	37.8%

* 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 1, 2015 and (ii) 1,750,000 shares of Common Stock and 875,000 shares of Common Stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 1, 2015 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 1, 2015 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 1, 2015 and are owned by ACP Partners, LP, which is beneficially-owned by Mr. Allen, (iii) 1,000,000 shares of Common Stock and 500,000 shares of Common Stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 1, 2015 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 1, 2015 and are owned by NYPPEX, LLC, which is beneficially owned by Mr. Allen, and (v) 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 1, 2015 and are owned by LGA Investments Family Limited Partnership, which is beneficially owned by Mr. Allen.

(3) Includes 306,955 shares of Common Stock issuable upon exercise of options that are exercisable within sixty days of March 1, 2015. Does not include 693,045 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2015.

(4) Includes (i) 875,000 shares of Common Stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 1, 2015 and (ii) 256,945 shares of Common Stock issuable upon exercise of options that are exercisable within sixty days of March 1, 2015. Does not include 318,055 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2015.

(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 1, 2015 and are owned by 1010 Holdings LLC, which is beneficially owned by Mr. Ferrari and (ii) 208,333 shares of Common Stock issuable upon exercise of options that are exercisable within sixty days of March 1, 2015. Does not include 251,667 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2015.

(6) Includes 162,499 shares of Common Stock issuable upon exercise of options that are exercisable within sixty days of March 1, 2015. Does not include 237,501 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2015.

(7) Includes (i) 2,013,816 shares of Common Stock issuable upon exercise of outstanding Warrants that are exercisable within sixty days of March 1, 2015, (ii) 175,000 shares of Common Stock issuable upon exercise of options that are exercisable within sixty days of March 1, 2015, (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 1, 2015 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 1, 2015 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 1, 2015 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 225,000 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2015.

(8) Includes (i) 683,438 shares held by Mr. Bobotas and 683,437 shares held by his wife and (ii) 290,287 shares of Common Stock issuable upon exercise of options that are exercisable within sixty days of March 1, 2015. Does not include 509,713 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2015.

(9) Includes 290,287 shares of Common Stock issuable upon exercise of options that are exercisable within sixty days of March 1, 2015. Does not include 509,713 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2015.

(10) Includes 97,778 shares of Common Stock issuable upon exercise of options that are exercisable within sixty days of March 1, 2015. Does not include 142,222 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2015.

(11) Includes 285,425 shares of Common Stock issuable upon exercise of options that are exercisable within 60 days of March 1, 2015. Does not include 589,575 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2015.

(12) Mr. Kling commenced employment with us on March 12, 2015 and therefore 350,000 shares of Common Stock underlying options granted after March 1, 2015 are not included in this table.

(13) See notes (4) 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, 2014.

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]	5,646,067	$ 1.05	2,603,933
Equity compensation plans not approved by security holders	500,000	$ 0.94	—
Total	6,146,067	$ 1.04	2,603,933

(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 1,291,706 shares were automatically made available for issuance on the first trading day of 2015, which represents 4% of the number of shares outstanding on December 31, 2014; 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, 2012, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed $120,000; 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.

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. See the section entitled "Description of Capital Stock –Warrants" for a discussion of the terms of the Private Placement Warrants.

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, totaling approximately $326,220. 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, 2014 and December 31, 2013, by EisnerAmper LLP, the Company's independent registered public accounting firm.

	Year Ended December 31,	
	2014	2013
	(in thousands)	
Audit Fees	$ 65	$ 21
Audit-related Fees	—	—
Tax Fees	4	8
All Other Fees	58	91
Total Fees	$ 127	$ 120

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.

All Other Fees are for professional services primarily relating to review of our registration statements.

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).

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).
10.1	Placement Agency Agreement, dated July 11, 2013, between the Company and Aegis Capital Corp. (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
10.2	Consulting Agreement, dated July 30, 2013, between the Company and Aegis Capital Corp. (incorporated by reference to Exhibit 10.2 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
10.3	Form of Subscription Agreement for the Company's 2013 private placement (incorporated by reference to Exhibit 10.3 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 Subscription Agreement for the Company's 2013 warrant private placement (incorporated by reference to Exhibit 10.4 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
10.5	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).
10.6	Matinas BioPharma Holdings, Inc. Amended and Restated 2013 Equity Compensation Plan*†
10.7	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). †
10.8	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 George Bobotas (incorporated by reference to Exhibit 10.10 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, 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). †
10.12	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). †

10.13	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). †
10.14	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). †
10.15	Form of Securities Purchase Agreement (Warrants) for the Company's formation private placement (incorporated by reference to Exhibit 10.15 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
10.16	Form of Securities Purchase Agreement (Units) for the Company's formation private placement (incorporated by reference to Exhibit 10.16 to Amendment No. 1 to the Company's Registration Statement on Form S-1 filed with the SEC on February 7, 2014).
10.17	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).
10.18	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.*+.
10.19	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). †
21.1	Subsidiaries Index*
23.1	Consent of EisnerAmper LLP*
31.1	Certification of President and Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
31.2	Certification of Acting Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1	Section 1350 Certifications**
101	The following financial information from the Annual Report on Form 10-K for the fiscal year ended December 31, 2014, formatted in XBRL (eXtensible Business Reporting Language), is filed electronically herewith: (i) Consolidated Balance Sheets as of December 31, 2014 and 2013; (ii) Consolidated Statements of Operations and Comprehensive Loss for the Years Ended December 31, 2014 and 2013; (iii) Consolidated Statement of Changes in Stockholders' Equity (Deficit) for the Years Ended December 31, 2014 and 2013; (iv) Consolidated Statements of Cash Flows for the Years Ended December 31, 2014 and 2013; 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, 2015.

MATINAS BIOPHARMA HOLDINGS, INC.

By: /s/ Roelof Rongen
Name: Roelof Rongen
Title: President & 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	President, Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2015
/s/ Gary Gaglione Gary Gaglione	Acting Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2015
/s/ Herbert Conrad Herbert Conrad	Chairman of the Board	March 30, 2015
/s/ Stefano Ferrari Stefano Ferrari	Director	March 30, 2015
/s/ James S. Scibetta James S. Scibetta	Director	March 30, 2015
/s/ Adam K. Stern Adam K. Stern	Director	March 30, 2015

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Report on the Consolidated Financial Statements

We have audited the accompanying consolidated financial statements of Matinas BioPharma Holdings, Inc. (the "Company"), which comprise the consolidated balance sheets as of December 31, 2014 and 2013, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years then ended, and the related notes to the consolidated financial statements.

Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the company's preparation and fair presentation of the financial statements in order to design 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. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Matinas BioPharma Holdings, Inc. as of December 31, 2014 and 2013, and the consolidated results of their operations and their cash flows for each of the years then ended in accordance with accounting principles generally accepted in the United States of America.

Emphasis of Matter

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 each period since inception, and these conditions have raised substantial doubt about its 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. Our opinion is not modified with respect to this matter.

/s/ EISNERAMPER LLP
Iselin, New Jersey
March 30, 2015

MATINAS BIOPHARMA HOLDINGS, INC.
Consolidated Balance Sheets

	December 31, 2014	December 31, 2013
ASSETS		
CURRENT ASSETS		
Cash and Cash Equivalents	$ 2,590,713	$ 10,840,428
Restricted Cash - current	100,000	-
Prepaid Expenses	114,425	84,493
Total Current Assets	2,805,138	10,924,921
Fixed Assets - net	339,995	93,057
Other assets including long term security deposit	216,317	315,778
TOTAL ASSETS	$ 3,361,450	$ 11,333,756
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 271,155	$ 396,768
Accrued Expenses	802,746	462,200
Lease Liability - Current	44,362	-
Total Current Liabilities	$ 1,118,263	$ 858,968
LONG TERM LIABILITIES		
Lease Liability - Long Term	$ 15,291	$ -
TOTAL LIABILITIES	$ 1,133,554	858,968
COMMITMENTS AND CONTINGENCIES (see Note H)		
STOCKHOLDERS' EQUITY		
Common Stock Par Value $ 0.0001, 150,000,000 Authorized, 32,292,650 Issued and outstanding as of December 31, 2014; 32,000,000 Issued and outstanding as of December 31, 2013	3,230	3,200
Additional Paid in Capital	16,276,430	14,302,307
Accumulated Deficit	(14,051,764)	(3,830,719)
Total Stockholders' Equity	2,227,896	10,474,788
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 3,361,450	$ 11,333,756

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

MATINAS BIOPHARMA HOLDINGS, INC.
Consolidated Statements of Operations

	For the Year Ended December 31,	
	2014	**2013**
OPERATING EXPENSES		
Research and development	**5,175,520**	**1,761,486**
General and administrative	**5,289,479**	**1,950,953**
Total Operating Expenses	**10,464,999**	**3,712,439**
Loss from Operations	**(10,464,999)**	**(3,712,439)**
Sale of New Jersey net operating losses	**269,127**	
Other expense, net	**(25,173)**	**(688)**
NET LOSS	**$ (10,221,045)**	**$ (3,713,127)**
BASIC AND DILUTED LOSS PER SHARE	**$ (0.32)**	**$ (0.20)**
WEIGHTED AVERAGE BASIC AND DILUTED NUMBER OF SHARES OUTSTANDING	**32,076,717**	**19,001,370**

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

MATINAS BIOPHARMA HOLDINGS, INC.
Consolidated Statement of Stockholders Equity
For the years ended December 31, 2014 and 2013

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid - in	Accumulated	Total Stockholders'
	(Shares)	(Amount)	(Shares)	(Amount)	Capital	Deficit	Deficit
Balance at December 31, 2012	925,926	$ 456,528	10,000,000	$ 1,000	-	($ 117,592)	($ 116,592)
Sale of Preferred Stock	925,926	500,001					
Issuance cost paid in connection of sale of preferred stock		(4,140)					
Formation of Matinas BioPharma Holdings (July 11, 2013)			7,500,000	750	374,250		375,000
Elimination of Matinas BioPharma Inc. Equity (July 11, 2013)	(1,851,852)	(952,389)	(10,000,000)	(1,000)			(1,000)
Issuance of shares in Matinas Holdings to former shareholders of Matinas BioPharma Inc			9,000,000	900	952,489		953,389
Sale of warrants					138,316		138,316
Private Placement (July 30, 2013 and August 8, 2013)			15,000,000	1,500	14,998,500		15,000,000
Private Placement Issuance Costs					(2,378,672)		(2,378,672)
Restricted Stock Grant to non-employee			500,000	50	469,950		470,000
Restricted Stock for services to be rendered					(463,562)		(463,562)
Stock Based Compensation - options					211,036		211,036
Net loss for the year ended December 31, 2013						(3,713,127)	(3,713,127)
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 services			292,650	30	152,721		$ 152,751
Net loss for the year ended December 31, 2014						(10,221,045)	$ (10,221,045)
Stock Holders Equity December 31, 2014	-	$ -	32,292,650	$ 3,230	$16,276,430	$ (14,051,764)	$ 2,227,896

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

MATINAS BIOPHARMA HOLDINGS, INC.
Consolidated Statements of Cash Flow

	For the Years Ended December 31,	
	2014	**2013**
Cash flows from operating activities:		
Net loss	$ (10,221,045)	$ (3,713,127)
Adjustments to reconcile net loss to net cash used by operating activities:		
Depreciation	41,581	1,131
Share based compensation	1,974,153	325,740
Changes in operating assets and liabilities		
Other assets	(539)	(315,778)
Prepaid expenses	(29,932)	(84,493)
Accrued expenses	400,199	462,250
Accounts payable	(125,613)	336,440
Net cash used in operating activities	(7,961,196)	(2,987,837)
Cash flows used by investing activities		
Equipment purchases	(288,519)	(94,188)
Net cash used in investing activities	(288,519)	(94,188)
Cash flows from financing activities:		
Repayment of loans provided by founders	-	(24,100)
Proceeds from redeemable convertible preferred stock issued for cash	-	500,001
Preferred stock issuance costs	-	(4,140)
Proceeds from common stock issued for cash	-	15,000,000
Common stock issuance costs	-	(2,378,672)
Proceeds from formation of holding's common stock	-	375,000
Proceeds from formation warrants	-	10,000
Proceeds from private placement warrants	-	20,000
Net cash provided by financing activities	-	13,498,089
Net (decrease) increase in cash equivalents	(8,249,715)	10,416,064
Cash and cash equivalents at beginning of period	10,840,428	424,364
Cash and cash equivalents at end of period	$ 2,590,713	$ 10,840,428
Supplemental non-cash financing activities		
Issuance of shares in Matinas Holdings (July 11, 2013)	$ -	953,389
Issuance of private placement warrants as consideration for equity issuance costs	-	1,252,111
Issuance of stock for services to be rendered	-	470,000
Capital lease for equipment purchase	111,095	-

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

MATINAS BIOPHARMA HOLDINGS, INC.
Notes to Financial Statements
(tabular dollars and shares in thousands, except per share data)

NOTE A - Company information and history

[1] Corporate History

Matinas BioPharma Holdings Inc. ("Holdings") a Delaware corporation formed in 2013. Holdings is the parent company of Matinas BioPharma, Inc., its operating subsidiary ("BioPharma" or "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 become a wholly owned subsidiary of Holdings (the "Merger") to effect its recapitalization plan. In connection with the Merger, the stockholders of BioPharma become 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. (See Note D for further discussion). For financial reporting purposes the accounting acquirer is BioPharma and accordingly, the historical financial statements of BioPharma are the continuing financial statements of the entity. In July and August of 2013, the Company completed a private placement of common stock, 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 (the "2013 Private Placement"). See Note D for further discussion. 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 Biotechnologies Inc., (referred to as the "Aquarius Merger" throughout this document and which is discussed in more detail under the section titled "Recent Developments" in Item 1 Business), 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 the development of targeted therapeutics using our innovative lipid-based drug delivery platform with an initial focus on the treatment of serious fungal and bacterial infections and the development of lipid-based prescription therapeutics for the treatment of cardiovascular and metabolic conditions. See subsequent event Note J for additional information on this transaction.

[2] Proprietary Products and Technology Portfolios

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.

Our lead product candidate for the treatment of infectious diseases is MAT 2203, an oral formulation of a broad spectrum anti-fungal drug called amphotericin B using our acquired cochleate delivery technology, for which a single-dose Phase 1a study has been completed. We expect to commence and complete 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, in 2015, with results expected in the fourth quarter of 2015. We are developing a pipeline of oral products by applying our cochleate delivery technology to a potentially broad array of established pharmaceuticals, including MAT 2501, an application of our cochleate delivery technology to a 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. We also continue to focus on identifying and developing novel pharmaceutical lipid-based products, including MAT9001 with an initial indication for the treatment of highly elevated triglycerides, or severe hypertriglyceridemia. Finally, our MAT8800 discovery program is seeking to identify and develop product candidates derived from omega-3 fatty acids for the treatment of non-alcoholic fatty liver disease for which there are currently no therapeutic solutions available.

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, 2014, the Company had an accumulated deficit of approximately $14 million. The Company's operations have been financed primarily through the sale of equity securities. The Company's net loss for the twelve months ended December 31, 2014 was approximately $10.2 million.

The Company has been engaged in developing MAT9001 since 2011. To date, the Company has not generated any revenue from MAT9001 and the Company expects to incur significant expenses to complete clinical work and to prepare MAT9001 for Phase III trials in the United States. The Company may never be able to obtain regulatory approval for the marketing of MAT9001 in any indication in the United States or internationally and even if the Company is able to commercialize MAT9001 or any other product candidate, there can be no assurance that the Company will generate significant revenues or ever achieve profitability.

Assuming the Company obtains FDA approval for MAT9001, which the Company does not expect to receive until 2017 at the earliest, the Company expects that its expenses will increase if the Company reaches commercial launch of MAT9001. The Company also expects that its research and development expenses will continue to increase as it moves forward for other indications for MAT9001 and diversifies its R&D portfolio. Furthermore, the Company expects that its research and development expenses will significantly increase as its MAT8800 discovery program progresses and advances to preclinical and clinical trials with one or more product candidates. In addition, on January 29, 2015 the Company acquired Aquarius Biotechnologies Inc. which will require additional investment to develop the technology acquired from Aquarius (please see Note J Subsequent Events). 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 initiate and complete its planned clinical and operational activities related to further development of MAT9001 and 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 on favorable terms, or at all. Without such additional funding, the Company is anticipating that the existing cash balance on hand at December 31, 2014 would not be sufficient to meet operating activities for the next twelve months. 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 its report on the Company's financial statements as of and for the year ended December 31, 2014 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 subsidiary, Matinas BioPharma Inc. Matinas BioPharma Inc. is the operational subsidiary 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.

[3] 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 various times throughout the period ended December 31, 2014, the Company's cash balances exceeded the FDIC insurance limit. The Company has not experienced any losses in such accounts.

[4] Property, Plant and Equipment

Property, plant and 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 property, plant, and equipment range 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.

[5] 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 2014 and 2013 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, 2014. 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, 2013 and 2014 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.

[6] 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 options 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. At the end of each financial reporting period prior to vesting, the value of these options, as calculated using the Black-Scholes option-pricing model, will be re-measured using the fair value of the Company's common stock and the non-cash expense recognized during the options granted to non-employees is subject to change in the future, the amount of the future expense will include fair value re-measurements until the stock options are fully vested.

The Company calculates the fair value of option grants utilizing the Black-Scholes pricing model, and estimates the fair value of the restricted stock based upon the estimated fair value or the common stock. The amount of stock-based compensation recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. The authoritative guidance requires forfeitures to be estimated at the time stock options are granted and warrants are issued and revised. 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.

For stock options issued to employees and members of the Board for their services on the Board, the Company estimates the grant date fair value of each option using the Black Scholes option pricing model. The use of the Black Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected term of the option, risk free interest rates, the value of the common stock and expected dividend yield of the common stock. For awards subject to service based vesting conditions, the Company recognizes stock based compensation expense equal to the grant date fair value of stock options on a straight line basis over the requisite service period, which is generally the vesting term. 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.

[7] 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.

[8] Basic Net Loss per Common Share

Basic net loss per common share is computed as net loss divided by the weighted average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss 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, 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 since their effect would be anti-dilutive, as of December 31, 2014 and 2013:

	2014	2013
Options that have been granted	5,353,417	3,160,000
Warrants (all granted during July 2013)	15,250,000	15,250,000
Total	**20,603,417**	**18,410,000**

[10] Revenue Recognition

The Company will develop an appropriate revenue recognition policy when planned anticipated future commercial operations commence.

[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 2014, the FASB issued ASU 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements. ASU 2014-10 eliminates the definition of a development stage entity in U.S accounting standards and removes all disclosure requirements, including the elimination of inception-to-date information on the statements of operations, cash flows and stockholders' equity related to the financial reporting distinction between development stage enterprises and other reporting entities. The amendments in ASU 2014-10 will be effective prospectively for annual reporting periods beginning after December 15, 2014, and interim periods within those annual periods, however, early adoption is permitted. The Company evaluated and adopted ASU 2014-10 for the Company's reporting period ended June 30, 2014 and therefore eliminated all incremental disclosures related to the Company's inception-to-date period.

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.

NOTE D - Formation and Reverse Acquisition of Matinas BioPharma Holdings

Formation

In May 2013, Holdings was formed solely to prepare the Company for the capital raising transaction described below under "2013 Private Placement". As part of the formation of Holdings, Holdings sold an aggregate of 7,500,000 shares of Holdings' common stock and 3,750,000 warrants to purchase 3,750,000 shares of its 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 its common stock to Adam Stern and entities owned by Mr. Stern. Mr. Stern is an affiliate of Aegis Capital Corp., the placement agent in Holdings' private placement in 2013 described below under 2013 Private Placement and a member of the board of directors of Holdings. The net cash proceeds of $375,000 has been reflected in the total equity for Holdings. The remaining 5,500,000 shares of its common stock and 2,250,000 warrants to purchase 2,250,000 shares of its common stock were sold to third parties, including certain representatives of Aegis Capital Corp., the placement agent for the 2013 Private Placement.

The aggregate proceeds of the units sold ($375,000 gross proceeds) were allocated between the warrants and the common stock based on their relative fair values which amounted to approximately $300,000 allocated to the common stock and $75,000 allocated to the warrants.

In addition, Holdings also offered and sold to Mr. Stern 250,000 warrants to purchase an additional 250,000 shares of its common stock at an exercise price of $2.00 per share, for which he paid $10,000 (at a purchase price of $0.04 per warrant) (the "Formation Warrants") for his effort in connection with the transaction. These additional Formation Warrants offered to Mr. Stern are compensatory for his services in connection with structuring the formation transaction and were sold at a lower price than the fair value of $0.47 per warrant. The difference of the fair value of the warrants and the cash proceeds in the amount of $108,316 was recorded as acquisition costs incurred in connection with this transaction, and included in the 2013 general and administrative expenses.

Merger

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 a wholly owned subsidiary of Holdings, 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 Holdings.

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 (approximately 28.5% of the issued common shares) of Holdings' common stock and warrants to purchase 1,000,000 shares of Holdings' common stock at an exercise price of $2.00 per share (the "Merger Warrants"). As a result of this Merger, the shareholders of Matinas BioPharma became shareholders of Holdings.

After consummation of the 2013 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, the Company 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).

2013 Private Placement

In July and August 2013, Holdings completed the 2013 Private Placement, under which it sold an aggregate of 15,000,000 shares of its common stock and warrants to purchase an aggregate of 7,500,000 shares of Holdings' 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 (the "Investor Warrants"). The aggregate gross proceeds of the units sold ($15.0 million gross proceeds) were allocated between the warrants and the common stock based on their relative fair values which amounted to approximately $11,983,000 allocated to the common stock and $3,017,000 allocated to the warrants. One of the units was sold to Mr. Herbert Conrad for the full offering price of $250,000, and consisted of 250,000 shares of common stock and 125,000 warrants.

Aegis Capital Corp. acted as the Placement Agent for the 2013 Private Placement. The gross proceeds to Holdings from the 2013 Private Placement were $15.0 million. In connection with the 2013 Private Placement, the Placement Agent received a cash placement agent fee of $1.5 million and a non-accountable expense allowance of $450,000. In addition, as part of its compensation for acting as placement agent for the 2013 Private Placement, Holdings issued (x) warrants to the Placement Agent to purchase 750,000 shares of its 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 its common stock with an exercise price of $1.00 per share. These warrants contain a "cashless exercise" feature and are exercisable at any time prior to July 30, 2018. The fair value of such warrants at the date of issuance was approximately $1.3 million using assumptions similar to those described in Note G and was recorded as part of equity, together with the other sales of common stock and warrants and not as a separate entry in the statement of stockholders equity for this stock issuance cost.

In connection with the closing of the 2013 Private Placement, the Placement Agent had a right to appoint one out of five members of Board of Directors of Holdings for a two-year term from the initial closing (the "Aegis Nominee"). Adam Stern 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 Holdings and the Voting Agreement described below. Holdings agreed to engage the Placement Agent as its warrant solicitation agent in the event the warrants, other than the Placement Agent 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.

After the consummation of the 2013 Merger and the 2013 Private Placement, the former shareholders of Matinas BioPharma held 28.5% of the common stock of Holdings by category of these transactions and approximately 30% when the additional shares purchased by Mr. Conrad in the 2013 Private Placement are included.

The private placement issuance cost totaled approximately $2.4 million of which $1.95 million was related to Placement Agent cash fees and expenses, $425,000 related to external legal costs and the remaining balance in other costs directly and incrementally attributable to the private placement funds raised. These costs are reflected as an offset to additional paid in capital.

Warrant Private Placement

Contemporaneously with the initial closing of the 2013 Private Placement, Holdings offered to all former preferred stockholders of Matinas BioPharma the right to purchase additional warrants with an exercise price of $2.00 per share of its common stock at a purchase price of $0.04 per warrant. Only Mr. Conrad exercised such right. As a result, Holdings sold 500,000 Private Placement Warrants to Mr. Conrad, for net cash proceeds of $20,000.

Summary of Changes in Capitalization

The following summarizes the capital structure before and after the 2013 Merger.

Investor Group	Matinas BioPharma Inc. (Accounting Acquirer)- Before	Holdings (Accounting Acquiree)- After
Former preferred and common shareholders	10,000,000 shares of common and 1,851,852 shares of preferred stock	9,000,000 shares of commons stock (28.6% of aggregate common stock holdings) and 1,500,000 warrants (1)
$0.10 unit purchasers, including Mr. Adam Stern and certain representatives of Aegis Capital	none	7,500,000 shares of commons stock (23.8% of aggregate common stock holdings) and 4,000,000 warrants (2)
2013 Private Placement Investors	none	15,000,000 shares of common stock (47.7% of the aggregate common stock holdings) and 7,500,000 warrants (3)
Aegis Capital Corporation	none	2,250,000 warrants

1. Includes 500,000 warrants purchased my Mr. Conrad - see Warrant Private Placement section.

2. Includes 2,250,000 warrants issued in connection with the placement agent fees, 3,750,000 issued in connection with the sale of units at the Formation and 250,000 warrants purchased by Mr. Stern - see section entitled “Formation”

3. From the 2013 Private Placement, and includes 1 unit purchased by Mr. Conrad for $ 250,000 at the full price paid by all third party investors.

Registration Rights and Other

In connection with the 2013 Private Placement, Holdings entered into a registration rights agreement with the private placement investors, the Placement Agent and the holders of its outstanding warrants. Holdings was required to file with the SEC no later than October 7, 2013 (the "Filing Deadline"), a registration statement covering the resale of the shares of common stock and the shares of common stock underlying the warrants, issued in the 2013 Private Placement, as well as the shares of common stock underlying the Formation Warrants, the Merger Warrants, and the Private Placement Warrants. The Company was also required to use commercially reasonable efforts to have the registration statement declared effective within one hundred and fifty (150) days after the registration statement was filed (the "Effectiveness Deadline"). 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 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 registrable securities covered by the registration statement can be sold under Rule 144 without any volume limitations (the "Effectiveness Period"). If this registration statement was not declared effective on or before the Effectiveness Deadline, Holdings would have been required to pay to each holder of registrable securities purchased in the 2013 Private Placement an amount in cash equal to one half of one percent (0.5%) of such holder's investment amount on every thirty (30) day anniversary of such Effectiveness Deadline until such failure was cured. The Company's registration statement was declared effective by the Securities and Exchange Commission on February 12, 2014, therefore no liability for the above provision had been recognized. The Company did maintain the effectiveness of the registration statement during the Effectiveness Period.

NOTE E – Fixed Assets

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

	December 31, 2014	December 31, 2013
Lab Equipment	**$ 245**	**74**
Furniture and Fixtures	**20**	**20**
Capitalized Leased Equipment	**111**	**0**
Leasehold Improvements	**7**	**0**
Total	**383**	**94**
Less accumulated depreciation	**43**	**1**
Fixed assets, net	**$ 340**	**$ 93**

In January 2014, the company entered a 24-month capital lease for lab equipment which has a buyout option of $ 1 at 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. Interest expense of $1,379 associated with the lease payments was recognized in the year ended December 31, 2014 to reflect 9 months of interest. Depreciation expense of $9,258 was recorded in the year.

NOTE F - Stock Holders Equity

Preferred Stock – Matinas BioPharma Inc.

As part of the formation and reverse acquisition of Matinas BioPharma Holdings discussed in Note D all authorized Preferred Shares of Matinas BioPharma Inc. were canceled and exchanged for Holdings' common shares. There were no shares of the redeemable convertible preferred stock outstanding at December 30, 2014, and this instrument is no longer authorized by the Company articles of incorporation.

Warrants

As of December 31, 2014, the Company had outstanding warrants to purchase an aggregate of 15,250,000 shares of common stock at exercise prices ranging from $1.00 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 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.

NOTE G - 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 8,250,000 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 End December 31,	
	2014	2013
Research and Development	$ 397	$ 82
General and Administrative	1,576	244
Total	$ 1,973	$ 326

In 2014, restricted stock grants totaling $ 616 thousand were granted to consultants and Board members and captured in G&A.

Stock Incentive Plans:

The following table contains information about the Company's stock plan at December 31, 2014:

	Awards Reserved for Issuance	**Awards Issued**	**Awards Available for Grant**
2013 Equity Compensation Plan	8,250,000	5,646,067*	2,603,933

* 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, 2013and 2014 (number of options in thousands):

	Number of Options	Weighted average exercise price	Weighted average contractual term in years
Outstanding at December 31, 2012	-	$ -	-
Granted	3,160	$ 0.94	
Exercised	-		
Forfeited	-		
Expired	-		
Outstanding at December 31, 2013	3,160	$ 0.94	9.7
Granted	2,413	$ 1.22	
Exercised	-		
Forfeited	(196)		
Expired	(24)		
Outstanding at December 31, 2014	5,353	$ 1.06	9.1

	Year ended December 31,	
	2014	2013
Options exercisable at end of year	2,460	321
Weighted average grant date fair value (per share) of options granted during the period	$ 0.68	$ 0.66

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. No milestones were met as of December 31, 2013.

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,	
	2014	2013
Volatility	68.76%	81.06%
Risk-free interest rate	1.65% - 1.93%	1.85% – 2.15%
Dividend yield	0.0%	0.0%
Expected life	4.75 – 5.5 years	5.0 – 6.0 years

The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding and is based on the options vesting term, contractual terms, and industry peers as the Company did not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.

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 revises, if necessary, were estimated based on management's expectation through industry knowledge and historical data.

During the year ended December 31, 2104, the Company issued 292,650 shares of restricted common stock to certain board of directors and consultants. The restricted stock issuances vested immediately and a total of approximately 211,300 was recorded to stock based compensation.

During the year 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.

As of December 31, 2014, the aggregate intrinsic value of in the money options was $0. The total intrinsic value is calculated as the difference between the Company's stock price on December 31, 2014 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, 2014, 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 2.0 years.

NOTE H – COMMMITMENTS

Lease Space

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, 2014 and 2013 was $95,500 and $0, respectively.

In December of 2014, the Company renewed its agreement to lease laboratory space for one year starting January 1, 2015 in Monmouth Junction, New Jersey at a monthly rent of $2,175.

Listed below is a summary of future lease rental payments as of December 31, 2014:

Fiscal Year Ending December 31,

	Lease Commitments
2015	154,140
2016	157,076
2017	160,014
2018	162,948
2019 and beyond	419,846
Total future minimum lease payments	$ 1,054,024

The Company was obligated to provide a security deposit of $300,000 to obtain lease space. Starting May 1, 2015, this deposit can be reduced by $100,000 on an annual basis, down to $50,000, as long as the Company makes timely rental payments.

On September 26, 2014 the Company entered into an agreement with a clinical research organization (CRO) to perform a Pharmacokinetic and Pharmacodynamic study. The total cost of the study is approximately $ 2 million dollars. To date, approximately $ 700 thousand has been paid towards the study, with the remaining balance due in increments between now and when the study is completed, which is estimated to be the end of May 2015.

NOTE I – 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, 2014 and December 31, 2013, 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,	
	2014	**2013**
Percent of pre-tax income:		
U.S. federal statutory income tax rate	34.0%	34.0%
State taxes, net of federal benefit	0.1%	-%
Permanent items	(3.1)%	(1.4)%
Research and development credit	0.9%	0.4%
Change in valuation allowance	(31.9)%	(33.0)%
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 2014 and 2013 consist of the following:

	As of December 31,	
	2014	**2013**
Deferred tax assets (liabilities)		
Share-based compensation	$ 489,017	$ 28,158
Intangible assets	88,764	9,103
Warrants	43,997	42,934
Accrued liability	-	60,048
Net operating loss carryforwards	4,379,541	1,318,000
Federal research and development credit carryforwards	241,318	24,425
Depreciation	(14,870)	-
Deferred income tax assets	5,227,767	1,482,668
Valuation allowance	(5,227,767)	(1,482,668)
Net deferred tax assets	$ 0	$ 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 $5.2 million and $1.5 million as of December 31, 2014 and 2013, respectively, representing an increase of $3.7 million.

As of December 31, 2014, the Company had Federal net operating loss carryforwards of $11.3 million. The Company also had federal and state research and development tax credit carryforwards of $241,000. 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 2014, the Company recognized a tax benefit of approximately $270,000 in connection with the sale of state net operating losses 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.

NOTE J- Subsequent Events

On January 29, 2015 the Company acquired Aquarius Biotechnologies, Inc. an innovative bio delivery drug discovery company with a novel and proprietary lipid-crystal nano-particle cochleate formulation technology platform. Aquarius became the wholly owned subsidiary of the Company on this date. The consideration for this acquisition is paid in three milestones. At closing, the Company issued the shareholders of Aquarius, 4,608,020 shares of the Company’s common stock, which is subject to adjust after the closing, under the terms of the agreement, up to 5,000,000 shares of the Company’s common stock based upon the closing balance sheet of Aquarius at the date of acquisition and other considerations. In addition, Aquarius shareholders have the ability to receive an additional 3,000,000 shares of the Company’s common stock based on future development and regulatory milestones related to Aquarius’ proprietary drug cochleate technology.

The transaction will be accounted for as a business combination, and accordingly the Company will include the results of operations of Aquarius subsequent to the January 29, 2015. The transaction is expected to result in a significant amount of in-process research and development on the balance sheet, subsequent to the transaction.

The acquisition of Aquarius Biotechnologies Inc., 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 the development of targeted therapeutics using our innovative lipid-based drug delivery platform with an initial focus on the treatment of serious fungal and bacterial infections and the development of lipid-based prescription therapeutics for the treatment of cardiovascular and metabolic conditions. Aquarius at the time of the transaction had one employee who will be retained by the Company.

Exhibit 10.6

MATINAS BIOPHARMA HOLDINGS, INC.

2013 EQUITY COMPENSATION PLAN

(As amended and restated effective as of May 8, 2014)

1. Establishment and Purpose

The purpose of the Matinas BioPharma Holdings, Inc. 2013 Equity Incentive Plan (the "Plan") is to provide a means whereby eligible employees, officers, non-employee directors and other individual service providers develop a sense of proprietorship and personal involvement in the development and financial success of the Company and to encourage them to devote their best efforts to the business of the Company, thereby advancing the interests of the Company and its stockholders. The Company, by means of the Plan, seeks to retain the services of such eligible persons and to provide incentives for such persons to exert maximum efforts for the success of the Company and its Subsidiaries.

The Plan permits the grant of Nonqualified Stock Options, Incentive Stock Options, Stock Appreciation Rights, Restricted Stock, Stock Units, Performance Shares, Performance Units, Incentive Bonus Awards, Other Cash-Based Awards and Other Stock-Based Awards. This Plan shall become effective upon the date set forth in Section 18.1 hereof.

2. Definitions

Wherever the following capitalized terms are used in the Plan, they shall have the meanings specified below:

2.1 "Affiliate" means, with respect to a Person, a Person that directly or indirectly Controls, or is Controlled by, or is under common Control with, such Person.

2.2 "Applicable Law" means the requirements relating to the administration of equity-based awards or equity compensation plans under U.S. state corporate laws, U.S. federal and state securities laws, the Code, any stock exchange or quotation system on which the Common Stock is listed or quoted and the applicable laws of any foreign country or jurisdiction where Awards are, or will be, granted under the Plan.

2.3 "Award" means an award of a Stock Option, Stock Appreciation Right, Restricted Stock, Stock Unit, Performance Share, Performance Unit, Incentive Bonus Award, Other Cash-Based Award and/or Other Stock-Based Award granted under the Plan.

2.4 "Award Agreement" means either (i) a written or electronic agreement entered into between the Company and a Participant setting forth the terms and conditions of an Award including any amendment or modification thereof, or (ii) a written or electronic statement issued by the Company to a Participant describing the terms and provisions of such Award, including any amendment or modification thereof. The Committee may provide for the use of electronic, internet or other non-paper Award Agreements, and the use of electronic, internet or other non-paper means for the acceptance thereof and actions thereunder by a Participant. Each Award Agreement shall be subject to the terms and conditions of the Plan and need not be identical.

2.5 "Board" means the Board of Directors of the Company.

2.6 "Cause" means (i) conviction of, or the entry of a plea of guilty or no contest to, a felony or any other crime that causes the Company or its Affiliates public disgrace or disrepute, or materially and adversely affects the Company's or its Affiliates' operations or financial performance or the relationship the Company has with its customers, (ii) gross negligence or willful misconduct with respect to the Company or any of its Affiliates, including, without limitation fraud, embezzlement, theft or proven dishonesty in the course of his or her employment; (iii) refusal to perform any lawful, material obligation or fulfill any duty (other than any duty or obligation of the type described in clause (v) below) to the Company or its Affiliates (other than due to a Disability), which refusal, if curable, is not cured within 10 days after delivery of written notice thereof; (iv) material breach of any agreement with or duty owed to the Company or any of its Affiliates, which breach, if curable, is not cured within 10 days after the delivery of written notice thereof; or (v) any breach of any obligation or duty to the Company or any of its Affiliates (whether arising by statute, common law or agreement) relating to confidentiality, noncompetition, nonsolicitation or proprietary rights. Notwithstanding the foregoing, if a Participant and the Company (or any of its Affiliates) have entered into an employment agreement, consulting agreement or other similar agreement that specifically defines "cause," then with respect to such Participant, "Cause" shall have the meaning defined in that employment agreement, consulting agreement or other agreement.

2.7 "Change in Control" means, unless otherwise provided in an Award Agreement, the occurrence of any one of the following events:

(i) any "person," including a "group" (as such terms are used in Sections 13(d) and 14(d) of the Exchange Act, but excluding the Company, any entity Controlling, Controlled by or under common Control with the Company, any trustee, fiduciary or other person or entity holding securities under any employee benefit plan or trust of the Company or any such entity, and, with respect to any particular Participant, the Participant and any "group" (as such term is used in Section 13(d)(3) of the Exchange Act) of which the Participant is a member), is or becomes the "beneficial owner" (as defined in Rule 13(d)(3) under the Exchange Act), directly or indirectly, of securities of the Company representing 50% or more of either (A) the combined voting power of the Company's then outstanding securities or (B) the then outstanding shares of Common Stock (in either such case other than as a result of an acquisition of securities directly from the Company); or

(ii) any consolidation or merger of the Company where the stockholders of the Company, immediately prior to the consolidation or merger, would not, immediately after the consolidation or merger, beneficially own (as such term is defined in Rule 13d-3 under the Exchange Act), directly or indirectly, shares representing in the aggregate 50% or more of the combined voting power of the securities of the corporation issuing cash or securities in the consolidation or merger (or of its ultimate parent corporation, if any); or

(iii) there shall occur (A) any sale, lease, exchange or other transfer (in one transaction or a series of transactions contemplated or arranged by any party as a single plan) of all or substantially all of the assets of the Company, other than a sale or disposition by the Company of all or substantially all of the Company's assets to an entity, at least 50% of the combined voting power of the voting securities of which are owned by "persons" (as defined above) in substantially the same proportion as their ownership of the Company immediately prior to such sale or (B) the approval by stockholders of the Company of any plan or proposal for the liquidation or dissolution of the Company; or

(iv) the members of the Board at the beginning of any consecutive 24-calendar-month period (the "Incumbent Directors") cease for any reason other than due to death to constitute at least a majority of the members of the Board; provided that any Director whose election, or nomination for election by the Company's stockholders, was approved or ratified by a vote of at least a majority of the members of the Board then still in office who were members of the Board at the beginning of such 24-calendar-month period, shall be deemed to be an Incumbent Director.

Notwithstanding the foregoing, no event or condition shall constitute a Change in Control to the extent that, if it were, a 20% tax would be imposed under Section 409A of the Code; provided that, in such a case, the event or condition shall continue to constitute a Change in Control to the maximum extent possible (e.g., if applicable, in respect of vesting without an acceleration of distribution) without causing the imposition of such 20% tax.

2.8 "Code" means the Internal Revenue Code of 1986, as amended. For purposes of this Plan, references to sections of the Code shall be deemed to include references to any applicable regulations thereunder and any successor or similar provision.

2.9 "Committee" means the committee of the Board delegated with the authority to administer the Plan, or the full Board, as provided in Section 3 of the Plan. With respect to any decision involving an Award intended to satisfy the requirements of Section 162(m) of the Code, the Committee shall consist of two or more directors of the Company who are "outside directors" within the meaning of Section 162(m) of the Code. With respect to any decision relating to a Reporting Person, the Committee shall consist solely of two or more directors who are disinterested within the meaning of Rule16b-3 promulgated under the Exchange Act, as amended from time to time, or any successor provision. The fact that a Committee member shall fail to qualify under any of these requirements shall not invalidate an Award if the Award is otherwise validly made under the Plan. The Board may at any time appoint additional members to the Committee, remove and replace members of the Committee with or without cause, and fill vacancies on the Committee however caused.

2.10 "Common Stock" means the Company's Common Stock, par value $.0001 per share.

2.11 "Company" means Matinas BioPharma Holdings, Inc., a Delaware corporation, and any successor thereto as provided in Section 16.8.

2.12 "Control" means, as to any Person, the power to direct or cause the direction of the management and policies of such Person, or the power to appoint directors of the Company, whether through the ownership of voting securities, by contract or otherwise (the terms "Controlled by", "Controlling" and "under common Control with" shall have correlative meanings).

2.13 "Date of Grant" means the date on which an Award under the Plan is granted by the Committee, or such later date as the Committee may specify to be the effective date of an Award.

2.14 "Disability" means a Participant being considered "disabled" within the meaning of Section 409A of the Code and Treasury Regulation 1.409A-3(i)(4), as well as any successor regulation or interpretation.

2.15 "Effective Date" means the date set forth in Section 18.1 hereof.

2.16 "Eligible Person" means 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 Committee to be a prospective employee, officer, director, consultant, advisor or other individual service provider of the Company or any Subsidiary.

2.17 "Exchange Act" means the Securities Exchange Act of 1934, as amended.

2.18 "Fair Market Value" of a share of Common Stock shall be, as applied to a specific date (i) the closing price of a share of Common Stock as of such date on the principal established stock exchange or national market system on which the Common Stock is then traded, or if there were no trades of the Common Stock recorded as of such date, then the most recent date preceding such date on which trades of the Common Stock were so recorded, or (ii) if the shares of Common Stock are not then traded on an established stock exchange or national market system but are then traded in an over-the-counter market, the average of the closing bid and asked prices for the shares of Common Stock in such over-the-counter market as of such date, or if there are no closing bid and asked prices for the shares of Common Stock in such over-the-counter market on such date, then the average of the closing 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 on such over-the-counter market, or (iii) if the shares of Common Stock are not then listed on a national securities exchange or national market system or traded in an over-the-counter market, the price of a share of Common Stock as determined by the Committee in its discretion in a manner consistent with Section 409A of the Code and Treasury Regulation 1.409A-1(b)(5)(iv), as well as any successor regulation or interpretation. Notwithstanding the foregoing, 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, in lieu of the determination of Fair Market Value under clauses (i) and (ii) above, the 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).

2.19 "Incentive Bonus Award" means an Award granted under Section 12 of the Plan.

2.20 "Incentive Stock Option" means a Stock Option granted under Section 6 hereof that is intended to meet the requirements of Section 422 of the Code and the regulations promulgated thereunder.

2.21 "Nonqualified Stock Option" means a Stock Option granted under Section 6 hereof that is not an Incentive Stock Option.

2.22 "Other Cash-Based Award" means a contractual right granted to an Eligible Person under Section 13 hereof entitling such Eligible Person to receive a cash payment at such times, and subject to such conditions, as are set forth in the Plan and the applicable Award Agreement.

2.23 "Other Stock-Based Award" means a contractual right granted to an Eligible Person under Section 13 representing a notional unit interest equal in value to a share of Common Stock to be paid and distributed at such times, and subject to such conditions as are set forth in the Plan and the applicable Award Agreement.

2.24 "Participant" means any Eligible Person who holds an outstanding Award under the Plan.

2.25 "Person" shall mean any individual, partnership, firm, trust, corporation, limited liability company or other similar entity. When two or more Persons act as a partnership, limited partnership, syndicate or other group for the purpose of acquiring, holding or disposing of Common Stock, such partnership, limited partnership, syndicate or group shall be deemed a "Person"

2.26 "Performance Measures" mean the measures of performance of the Company and its Subsidiaries as more fully described in Section 14 of the Plan and Exhibit A hereto.

2.27 "Performance Shares" means a contractual right granted to an Eligible Person under Section 10 hereof representing a notional unit interest equal in value to a share of Common Stock to be paid and distributed at such times, and subject to such conditions, as are set forth in the Plan and the applicable Award Agreement.

2.28 "Performance Unit" means a contractual right granted to an Eligible Person under Section 11 hereof representing a notional dollar interest as determined by the Committee to be paid and distributed at such times, and subject to such conditions, as are set forth in the Plan and the applicable Award Agreement.

2.29 "Plan" means this Matinas BioPharma Holdings, Inc. 2013 Equity Incentive Plan, as it may be amended from time to time.

2.30 "Reporting Person" means an officer, director or greater than ten percent stockholder of the Company within the meaning of Rule 16a-2 under the Exchange Act, who is required to file reports pursuant to Rule 16a-3 under the Exchange Act.

2.31 "Restricted Stock Award" means a grant of shares of Common Stock to an Eligible Person under Section 8 hereof that are issued subject to such vesting and transfer restrictions and such other conditions as are set forth in the Plan and the applicable Award Agreement.

2.32 "Securities Act" means the Securities Act of 1933, as amended.

2.33 "Service" means a Participant's employment or other service relationship with the Company or any Subsidiary.

2.34 "Stock Appreciation Right" means a contractual right granted to an Eligible Person under Section 7 hereof entitling such Eligible Person to receive a payment, upon the exercise of such right, in such amount and at such time, and subject to such conditions, as are set forth in the Plan and the applicable Award Agreement.

2.35 "Stock Option" means a contractual right granted to an Eligible Person under Section 6 hereof to purchase shares of Common Stock at such time and price, and subject to such conditions, as are set forth in the Plan and the applicable Award Agreement.

2.36 "Stock Unit Award" means a contractual right granted to an Eligible Person under Section 9 hereof representing notional unit interests equal in value to a share of Common Stock to be paid and distributed at such times, and subject to such conditions, as are set forth in the Plan and the applicable Award Agreement.

2.37 "Stockholders" Agreement" means an agreement between a Participant and the Company as contemplated by Section 16.11.

2.38 "Subsidiary" means an entity (whether or not a corporation) that is wholly or majority owned or controlled, directly or indirectly, by the Company; provided, however, that with respect to Incentive Stock Options, the term "Subsidiary" shall include only an entity that qualifies under section 424(f) of the Code as a "subsidiary corporation" with respect to the Company.

3. Administration

3.1 Committee Members. The Plan shall be administered by the Committee; provided that the entire Board may act in lieu of the Committee on any matter, subject to Code Section 162(m) and 16b-3 Award requirements referred to in Section 2.9 of the Plan. If and to the extent permitted by Applicable Law, the Committee may authorize one or more Reporting Persons (or other officers) to make Awards to Eligible Persons who are not Reporting Persons (or other officers whom the Committee has specifically authorized to make Awards). Subject to Applicable Law and the restrictions set forth in the Plan, the Committee may delegate administrative functions to individuals who are Reporting Persons, officers, or employees of the Company or its Subsidiaries.

3.2 Committee Authority. The Committee shall have such powers and authority as may be necessary or appropriate for the Committee to carry out its functions as described in the Plan. Subject to the express limitations of the Plan, the Committee shall have authority in its discretion to determine the Eligible Persons to whom, and the time or times at which, Awards may be granted, the number of shares, units or other rights subject to each Award, the exercise, base or purchase price of an Award (if any), the time or times at which an Award will become vested, exercisable or payable, the performance criteria, performance goals and other conditions of an Award, the duration of the Award, and all other terms of the Award. Subject to the terms of the Plan, the Committee shall have the authority to amend the terms of an Award in any manner that is not inconsistent with the Plan (including to extend the post-termination exercisability period of Stock Options and Stock Appreciation Rights), provided that no such action shall adversely affect the rights of a Participant with respect to an outstanding Award without the Participant's consent. The Committee shall also have discretionary authority to interpret the Plan, to make all factual determinations under the Plan, and to make all other determinations necessary or advisable for Plan administration, including, without limitation, to correct any defect, to supply any omission or to reconcile any inconsistency in the Plan or any Award Agreement hereunder. The Committee may prescribe, amend, and rescind rules and regulations relating to the Plan. The Committee's determinations under the Plan need not be uniform and may be made by the Committee selectively among Participants and Eligible Persons, whether or not such persons are similarly situated. The Committee shall, in its discretion, consider such factors as it deems relevant in making its interpretations, determinations and actions under the Plan including, without limitation, the recommendations or advice of any officer or employee of the Company or such attorneys, consultants, accountants or other advisors as it may select. All interpretations, determinations, and actions by the Committee shall be final, conclusive, and binding upon all parties.

3.3 No Liability; Indemnification. Neither the Board nor any Committee member, nor any Person acting at the direction of the Board or the Committee, shall be liable for any act, omission, interpretation, construction or determination made in good faith with respect to the Plan, any Award or any Award Agreement. The Company and its Subsidiaries shall pay or reimburse any member of the Committee, as well as any other Person who takes action on behalf of the Plan, for all reasonable expenses incurred with respect to the Plan, and to the full extent allowable under Applicable Law shall indemnify each and every one of them for any claims, liabilities, and costs (including reasonable attorney's fees) arising out of their good faith performance of duties on behalf of the Company with respect to the Plan. The Company and its Subsidiaries may, but shall not be required to, obtain liability insurance for this purpose.

4. Shares Subject to the Plans

4.1 Share Limitation.

(a) Subject to adjustment pursuant to Section 4.2 hereof and any other applicable provisions hereof, the maximum aggregate number of shares of Common Stock which may be issued under all Awards granted to Participants under the Plan shall be 8,250,000 shares (the "Initial Limit"), all of which may, but need not, be issued in respect of Incentive Stock Options. The number of shares of Common Stock available for issuance under the Plan shall 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 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 shall be equal to the Initial Limit, and shall be increased on each January 1, commencing on January 1, 2015, by the Annual Increase for such calendar year.

(b) Shares of Common Stock issued under the Plan may be either authorized but unissued shares or shares held in the Company's treasury. Any shares of Common Stock subject to Awards that are settled in Common Stock shall be counted against the maximum share limitations of this Section 4.1 as one share of Common Stock for every share of Common Stock subject thereto, regardless of the number of shares of Common Stock actually issued to settle the Stock Option or Stock Appreciation Right upon exercise. To the extent that any Award under the 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 no longer be counted against the foregoing maximum share limitations and may again be made subject to Awards under the Plan pursuant to such limitations. 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 no longer be counted against the foregoing maximum share limitations and may again be made subject to Awards under the Plan pursuant to such limitations.

4.2 Adjustments. If there shall occur any change with respect to the outstanding shares of Common Stock by reason of any recapitalization, reclassification, stock dividend, extraordinary dividend, stock split, reverse stock split, or other distribution with respect to the shares of Common Stock, or any merger, reorganization, consolidation, combination, spin-off or other similar corporate change, or any other change affecting the Common Stock, the Committee shall, in the manner and to the extent that it deems appropriate and equitable to the Participants and consistent with the terms of the Plan, cause an adjustment to be made in (i) the maximum numbers and kind of shares provided in Section 4.1 hereof, (ii) the numbers and kind of shares of Common Stock, units, or other rights subject to then outstanding Awards, (iii) the price for each share or unit or other right subject to then outstanding Awards, (iv) the performance measures or goals relating to the vesting of an Award and (v) any other terms of an Award that are affected by the event to prevent dilution or enlargement of a Participant's rights under an Award. Notwithstanding the foregoing, in the case of Incentive Stock Options, any such adjustments shall, to the extent practicable, be made in a manner consistent with the requirements of Section 424(a) of the Code.

5. Participation and Awards

5.1 Designation of Participants. All Eligible Persons are eligible to be designated by the Committee to receive Awards and become Participants under the Plan. The Committee has the authority, in its discretion, to determine and designate from time to time those Eligible Persons who are to be granted Awards, the types of Awards to be granted and the number of shares of Common Stock or units subject to Awards granted under the Plan. In selecting Eligible Persons to be Participants and in determining the type and amount of Awards to be granted under the Plan, the Committee shall consider any and all factors that it deems relevant or appropriate.

5.2 Determination of Awards. The Committee shall determine the terms and conditions of all Awards granted to Participants in accordance with its authority under Section 3.2 hereof. An Award may consist of one type of right or benefit hereunder or of two or more such rights or benefits granted in tandem or in the alternative. To the extent deemed appropriate by the Committee, an Award shall be evidenced by an Award Agreement as described in Section 16.1 hereof.

6. Stock Options

6.1 Grant of Stock Option. A Stock Option may be granted to any Eligible Person selected by the Committee. Subject to the provisions of Section 6.6 hereof and Section 422 of the Code, each Stock Option shall be designated, in the discretion of the Committee, as an Incentive Stock Option or as a Nonqualified Stock Option.

6.2 Exercise Price. The exercise price per share of a Stock Option shall not be less than 100% of the Fair Market Value of a share of Common Stock with respect to the Date of Grant of such Stock Option, subject to adjustments as provided for under Section 4.2, provided that the Committee may in its discretion specify for any Stock Option an exercise price per share that is higher than the Fair Market Value on the Date of Grant.

6.3 Vesting of Stock Options. The Committee shall in its discretion prescribe the time or times at which, or the conditions upon which, a Stock Option or portion thereof shall become vested and/or exercisable. The requirements for vesting and exercisability of a Stock Option may be based on the continued Service of the Participant with the Company or a Subsidiary for a specified time period (or periods) and/or on the attainment of a specified performance goal (or goals) established by the Committee in its discretion. The Committee may, in its discretion, accelerate the vesting or exercisability of any Stock Option at any time. The Committee in its sole discretion may allow a Participant to exercise unvested Nonqualified Stock Options, in which case the shares of Common Stock then issued shall be Restricted Stock having analogous vesting restrictions to the unvested Nonqualified Stock Options.

6.4 Term of Stock Options. The Committee shall in its discretion prescribe in an Award Agreement the period during which a vested Stock Option may be exercised, provided that the maximum term of a Stock Option shall be ten (10) years from the Date of Grant. A Stock Option may be earlier terminated as specified by the Committee and set forth in an Award Agreement upon or following the termination of a Participant's Service with the Company or any Subsidiary, including by reason of voluntary resignation, death, Disability, termination for Cause or any other reason. Except as otherwise provided in this Section 6 or in an Award Agreement as such agreement may be amended from time to time upon authorization of the Committee, no Stock Option may be exercised at any time during the term thereof unless the Participant is then in the Service of the Company or one of its Subsidiaries.

6.5 Stock Option Exercise. Subject to such terms and conditions as shall be specified in an Award Agreement, a Stock Option may be exercised in whole or in part at any time during the term thereof by notice in the form required by the Company, and payment of the aggregate exercise price by certified or bank check, or such other means as the Committee may accept. As set forth in an Award Agreement or otherwise determined by the Committee, in its sole discretion, at or after grant, payment in full or in part of the exercise price of an Option may be made: (i) in the form of shares of Common Stock that have been held by the Participant for such period as the 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 Committee in connection with the Plan; and/or (iv) by such other method as may be approved by the Committee and set forth in an Award Agreement. Subject to any governing rules or regulations, as soon as practicable after receipt of written notification of exercise and full payment of the exercise price and satisfaction of any applicable tax withholding pursuant to Section 17.5, the Company shall deliver to the Participant evidence of book entry shares of Common Stock, or upon the Participant's request, Common Stock certificates in an appropriate amount based upon the number of shares of Common Stock purchased under the Option. Unless otherwise determined by the Committee, all payments under all of the methods indicated above shall be paid in United States dollars or shares of Common Stock, as applicable.

6.6 Additional Rules for Incentive Stock Options.

(a) Eligibility. An Incentive Stock Option may only be granted to an Eligible Person who is considered an employee under Treasury Regulation §1.421-7(h) of the Company or any Subsidiary.

(b) Annual Limits. No Incentive Stock Option shall be granted to an Eligible Person as a result of which the aggregate Fair Market Value (determined as of the Date of Grant) of the stock with respect to which Incentive Stock Options are exercisable for the first time in any calendar year under the Plan and any other stock option plans of the Company or any Subsidiary would exceed $100,000, determined in accordance with Section 422(d) of the Code. This limitation shall be applied by taking Incentive Stock Options into account in the order in which granted.

(c) Ten Percent Stockholders. If a Stock Option granted under the Plan is intended to be an Incentive Stock Option, and if the Participant, at the time of grant, owns stock possessing ten percent or more of the total combined voting power of all classes of Common Stock of the Company or any Subsidiary, then (A) the Stock Option exercise price per share shall in no event be less than 110% of the Fair Market Value of the Common Stock on the date of such grant and (B) such Stock Option shall not be exercisable after the expiration of five (5) years following the date such Stock Option is granted.

(d) Termination of Employment. An Award of an Incentive Stock Option shall provide that such Stock Option may be exercised not later than three (3) months following termination of employment of the Participant with the Company and all Subsidiaries, or not later than one (1) year following death or a permanent and total disability within the meaning of Section 22(e)(3) of the Code, as and to the extent determined by the Committee to comply with the requirements of Section 422 of the Code.

(e) Disqualifying Dispositions. If shares of Common Stock acquired by exercise of an Incentive Stock Option are disposed of within two (2) years following the Date of Grant or one (1) year following the transfer of such shares to the Participant upon exercise, the Participant shall, promptly following such disposition, notify the Company in writing of the date and terms of such disposition and provide such other information regarding the disposition as the Company may reasonably require.

7. Stock Appreciation Rights

7.1 Grant of Stock Appreciation Rights. A Stock Appreciation Right may be granted to any Eligible Person selected by the Committee. Stock Appreciation Rights may be granted on a basis that allows for the exercise of the right by the Participant or that provides for the automatic payment of the right upon a specified date or event.

7.2 Base Price. The base price of a Stock Appreciation Right shall be determined by the Committee in its sole discretion; provided, however, that the base price for any grant of a Stock Appreciation Right shall not be less than 100% of the Fair Market Value of a share of Common Stock with respect to the Date of Grant of such Stock Appreciation Right, subject to adjustments as provided for under Section 4.2.

7.3 Vesting Stock Appreciation Rights. The Committee shall in its discretion prescribe the time or times at which, or the conditions upon which, a Stock Appreciation Right or portion thereof shall become vested and/or exercisable. The requirements for vesting and exercisability of a Stock Appreciation Right may be based on the continued Service of a Participant with the Company or a Subsidiary for a specified time period (or periods) or on the attainment of a specified performance goal (or goals) established by the Committee in its discretion. The Committee may, in its discretion, accelerate the vesting or exercisability of any Stock Appreciation Right at any time.

7.4 Term of Stock Appreciation Rights. The Committee shall in its discretion prescribe in an Award Agreement the period during which a vested Stock Appreciation Right may be exercised, provided that the maximum term of a Stock Appreciation Right shall be ten (10) years from the Date of Grant. A Stock Appreciation Right may be earlier terminated as specified by the Committee and set forth in an Award Agreement upon or following the termination of a Participant's Service with the Company or any Subsidiary, including by reason of voluntary resignation, death, Disability, termination for Cause or any other reason. Except as otherwise provided in this Section 7 or in an Award Agreement as such agreement may be amended from time to time upon authorization of the Committee, no Stock Appreciation Right may be exercised at any time during the term thereof unless the Participant is then in the Service of the Company or one of its Subsidiaries.

7.5 Payment of Stock Appreciation Rights. Subject to such terms and conditions as shall be specified in an Award Agreement, a vested Stock Appreciation Right may be exercised in whole or in part at any time during the term thereof by notice in the form required by the Company and payment of any exercise price. Upon the exercise of a Stock Appreciation Right and payment of any applicable exercise price, a Participant shall be entitled to receive an amount determined by multiplying: (i) 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, by (ii) the number of shares as to which such Stock Appreciation Right is exercised. Payment of the amount determined under the immediately preceding sentence may be made, as approved by the Committee and set forth in the Award Agreement, in shares of Common Stock valued at their Fair Market Value on the date of exercise, in cash, or in a combination of shares of Common Stock and cash, subject to applicable tax withholding requirements set forth in Section 17.5. If Stock Appreciation Rights are settled in shares of Common Stock, then as soon as practicable following the date of settlement the Company shall deliver to the Participant evidence of book entry shares of Common Stock, or upon the Participant's request, Common Stock certificates in an appropriate amount.

8. Restricted Stock Awards

8.1 Grant of Restricted Stock Awards. A Restricted Stock Award may be granted to any Eligible Person selected by the Committee. The Committee may require the payment by the Participant of a specified purchase price in connection with any Restricted Stock Award. The Committee may provide in an Award Agreement for the payment of dividends and distributions to the Participant at such times as paid to stockholders generally or at the times of vesting or other payment of the Restricted Stock Award. If any dividends or distributions are paid in stock while a Restricted Stock Award is subject to restrictions under Section 8.3 of the Plan or Code Section 162(m), the dividends or other distributions shares shall be subject to the same restrictions on transferability as the shares of Common Stock to which they were paid unless otherwise set forth in the Award Agreement. The Committee may also subject the grant of any Restricted Stock Award to the execution of a voting agreement with the Company or with any Affiliate of the Company.

8.2 Vesting Requirements. The restrictions imposed on shares of Common Stock granted under a Restricted Stock Award shall lapse in accordance with the vesting requirements specified by the Committee in the Award Agreement. Upon vesting of a Restricted Stock Award, such Award shall be subject to the tax withholding requirement set forth in Section 17.5. The requirements for vesting of a Restricted Stock Award may be based on the continued Service of the Participant with the Company or its Subsidiaries for a specified time period (or periods) or on the attainment of a specified performance goal (or goals) established by the Committee in its discretion. The Committee may, in its discretion, accelerate the vesting of a Restricted Stock Award at any time. If the vesting requirements of a Restricted Stock Award shall not be satisfied, the Award shall be forfeited and the shares of Common Stock subject to the Award shall be returned to the Company. In the event that the Participant paid any purchase price with respect to such forfeited shares, unless otherwise provided by the Committee in an Award Agreement, the Company will refund to the Participant the lesser of (i) such purchase price and (ii) the Fair Market Value of such shares on the date of forfeiture.

8.3 Restrictions. Shares granted under any Restricted Stock Award may not be transferred, assigned or subject to any encumbrance, pledge, or charge until all applicable restrictions are removed or have expired, unless otherwise allowed by the Committee. The Committee may require in an Award Agreement that certificates representing the shares granted under a Restricted Stock Award bear a legend making appropriate reference to the restrictions imposed, and that certificates representing the shares granted or sold under a Restricted Stock Award will remain in the physical custody of an escrow holder until all restrictions are removed or have expired.

8.4 Rights as Stockholder. Subject to the foregoing provisions of this Section 8 and the applicable Award Agreement, the Participant to whom a Restricted Stock Award is made shall have all rights of a stockholder with respect to the shares granted to the Participant under the Restricted Stock Award, including the right to vote the shares and receive all dividends and other distributions paid or made with respect thereto, unless the Committee determines otherwise at the time the Restricted Stock Award is granted.

8.5 Section 83(b) Election. If a Participant makes an election pursuant to Section 83(b) of the Code with respect to a Restricted Stock Award, the Participant shall file, within 30 days following the Date of Grant, a copy of such election with the Company (directed to the Secretary thereof) and with the Internal Revenue Service, in accordance with the regulations under Section 83 of the Code. The Committee may provide in an Award Agreement that the Restricted Stock Award is conditioned upon the Participant's making or refraining from making an election with respect to the Award under Section 83(b) of the Code.

9. Stock Unit Awards

9.1 Grant of Stock Unit Awards. A Stock Unit Award may be granted to any Eligible Person selected by the Committee. The value of each stock unit under a Stock Unit Award is equal to the Fair Market Value of the Common Stock on the applicable date or time period of determination, as specified by the Committee. A Stock Unit Award shall be subject to such restrictions and conditions as the Committee shall determine. A Stock Unit Award may be granted together with a dividend equivalent right with respect to the shares of Common Stock subject to the Award, which may be accumulated and may be deemed reinvested in additional stock units, as determined by the Committee in its discretion. If any dividend equivalents are paid while a Stock Unit Award is subject to restrictions under Section 9 of the Plan or Code Section 162(m), the dividend equivalents shall be subject to the same restrictions on transferability as the Stock Units to which they were paid, unless otherwise set forth in the Award Agreement.

9.2 Vesting of Stock Unit Awards. On the Date of Grant, the Committee shall, in its discretion, determine any vesting requirements with respect to a Stock Unit Award, which shall be set forth in the Award Agreement. The requirements for vesting of a Stock Unit Award may be based on the continued Service of the Participant with the Company or its Subsidiaries for a specified time period (or periods) or on the attainment of a specified performance goal (or goals) established by the Committee in its discretion. The Committee may, in its discretion, accelerate the vesting of a Stock Unit Award at any time. A Stock Unit Award may also be granted on a fully vested basis, with a deferred payment date as may be determined by the Committee or elected by the Participant in accordance with rules established by the Committee.

9.3 Payment of Stock Unit Awards. A Stock Unit Award shall become payable to a Participant at the time or times determined by the Committee and set forth in the Award Agreement, which may be upon or following the vesting of the Award. Payment of a Stock Unit Award may be made, at the discretion of the Committee, in cash or in shares of Common Stock, or in a combination thereof as described in the Award Agreement, subject to applicable tax withholding requirements set forth in Section 17.5. Any cash payment of a Stock Unit Award shall be made based upon the Fair Market Value of the Common Stock, determined on such date or over such time period as determined by the Committee. Notwithstanding the foregoing, unless specified otherwise in the Award Agreement, any Stock Unit, whether settled in Common Stock or cash, shall be paid no later than two and one-half months after the later of the calendar year or fiscal year in which the Stock Units vest. If Stock Unit Awards are settled in shares of Common Stock, then as soon as practicable following the date of settlement, the Company shall deliver to the Participant evidence of book entry shares of Common Stock, or upon the Participant's request, Common Stock certificates in an appropriate amount.

10. Performance Shares

10.1 Grant of Performance Shares. Performance Shares may be granted to any Eligible Person selected by the Committee. A Performance Share Award shall be subject to such restrictions and condition as the Committee shall specify. A Performance Share Award may be granted with a dividend equivalent right with respect to the shares of Common Stock subject to the Award, which may be accumulated and may be deemed reinvested in additional stock units, as determined by the Committee in its discretion.

10.2 Value of Performance Shares. Each Performance Share shall have an initial value equal to the Fair Market Value of a Share on the Grant Date. The Committee shall set performance goals in its discretion that, depending on the extent to which they are met over a specified time period, shall determine the number of Performance Shares that shall be paid to a Participant.

10.3 Earning of Performance Shares. After the applicable time period has ended, the number of Performance Shares earned by the Participant over such time period shall be determined as a function of the extent to which the applicable corresponding performance goals have been achieved. This determination shall be made solely by the Committee. The Committee may, in its discretion, waive any performance or vesting conditions relating to a Performance Share Award.

10.4 Form and Timing of Payment of Performance Shares. The Committee shall pay at the close of the applicable Performance Period, or as soon as practicable thereafter, any earned Performance Shares in the form of cash or in shares of Common Stock or in a combination thereof, as specified in a Participant's Award Agreement, subject to applicable tax withholding requirements set forth in Section 17.5. Notwithstanding the foregoing, all Performance Shares shall be paid no later than two and one-half months following the later of the calendar year or fiscal year in which such Performance Shares vest. Any shares of Common Stock paid to a Participant under this Section 10.4 may be subject to any restrictions deemed appropriate by the Committee. If Performance Shares are settled in shares of Common Stock, then as soon as practicable following the date of settlement the Company shall deliver to the Participant evidence of book entry shares of Common Stock, or upon the Participant's request, Common Stock certificates in an appropriate amount.

11. Performance Units

11.1 Grant of Performance Units. Performance Units may be granted to any Eligible Person selected by the Committee. A Performance Unit Award shall be subject to such restrictions and condition as the Committee shall specify in a Participant's Award Agreement.

11.2 Value of Performance Units. Each Performance Unit shall have an initial notional value equal to a dollar amount determined by the Committee, in its sole discretion. The Committee shall set performance goals in its discretion that, depending on the extent to which they are met over a specified time period, will determine the number of Performance Units that shall be settled and paid to the Participant.

11.3 Earning of Performance Units. After the applicable time period has ended, the number of Performance Units earned by the Participant, and the amount payable in cash, in shares or in a combination thereof, over such time period shall be determined as a function of the extent to which the applicable corresponding performance goals have been achieved. This determination shall be made solely by the Committee. The Committee may, in its discretion, waive any performance or vesting conditions relating to a Performance Unit Award

11.4 Form and Timing of Payment of Performance Units. The Committee shall pay at the close of the applicable Performance Period, or as soon as practicable thereafter, any earned Performance Units in the form of cash or in shares of Common Stock or in a combination thereof, as specified in a Participant's Award Agreement, subject to applicable tax withholding requirements set forth in Section 17.5. Notwithstanding the foregoing, all Performance Units shall be paid no later than two and one-half months following the later of the calendar year or fiscal year in which such Performance Units vest. Any shares of Common Stock paid to a Participant under this Section 11.4 may be subject to any restrictions deemed appropriate by the Committee. If Performance Units are settled in shares of Common Stock, then as soon as practicable following the date of settlement the Company shall deliver to the Participant evidence of book entry shares of Common Stock, or upon the Participant's request, Common Stock certificates in an appropriate amount.

12. Incentive Bonus Awards

12.1 Incentive Bonus Awards. The Committee, at its discretion, may grant Incentive Bonus Awards to such Participants as it may designate from time to time. The terms of a Participant's Incentive Bonus Award shall be set forth in the Participant's Award Agreement. Each Award Agreement shall specify such general terms and conditions as the Committee shall determine.

12.2 Incentive Bonus Award Performance Criteria. The determination of Incentive Bonus Awards for a given year or years 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 Committee, including any or all of the Performance Measures set forth in Exhibit A hereto. The Committee shall (i) select those Participants who shall be eligible to receive an Incentive Bonus Award, (ii) determine the performance period, (iii) determine target levels of performance, and (iv) determine the level of Incentive Bonus Award to be paid to each selected Participant upon the achievement of each performance level. The Committee generally shall make the foregoing determinations prior to the commencement of services to which an Incentive Bonus Award relates (or for Incentive Bonus Awards intended to satisfy Code Section 162(m), within the permissible time period established for exemption under Code Section 162(m) and the regulations promulgated thereunder), to the extent applicable, and while the outcome of the performance goals and targets is uncertain.

12.3 Payment of Incentive Bonus Awards.

(a) Incentive Bonus Awards shall be paid in cash or Common Stock, as set forth in a Participant's Award Agreement. Payments shall be made following a determination by the Committee that the performance targets were attained and shall be made within two and one-half months after the later of the end of the fiscal or calendar year in which the Incentive Award is no longer subject to a substantial risk of forfeiture.

(b) The amount of an Incentive Bonus Award to be paid upon the attainment of each targeted level of performance shall equal a percentage of a Participant's base salary for the fiscal year, a fixed dollar amount, or such other formula, as determined by the Committee.

13. Other Cash-Based Awards and Other Stock-Based Awards

13.1 Other Cash-Based and Stock-Based Awards. The Committee may grant other types of equity-based or equity-related Awards not otherwise described by the terms of this Plan (including the grant or offer for sale of unrestricted Shares) in such amounts and subject to such terms and conditions, as the Committee shall determine. Such Awards may involve the transfer of actual shares of Common Stock to a Participant, or payment in cash or otherwise of amounts based on the value of shares of Common Stock. In addition, the Committee, at any time and from time to time, may grant Cash-Based Awards to a Participant in such amounts and upon such terms as the Committee shall determine, in its sole discretion.

13.2 Value of Cash-Based Awards and Other Stock-Based Awards. Each Other Stock-Based Award shall be expressed in terms of shares of Common Stock or units based on shares of Common Stock, as determined by the Committee, in its sole discretion. Each Other Cash-Based Award shall specify a payment amount or payment range as determined by the Committee, in its sole discretion. If the Committee exercises its discretion to establish performance goals, the value of Other Cash-Based Awards that shall be paid to the Participant will depend on the extent to which such performance goals are met.

13.3 Payment of Cash-Based Awards and Other Stock-Based Awards. Payment, if any, with respect to Other Cash-Based Awards and Other Stock-Based Award shall be made in accordance with the terms of the Award, in cash or Shares as the Committee determines.

14. Code Section 162(m) Awards

14.1 Awards Granted Under Code Section 162(m). The Committee, at its discretion, may designate that a Restricted Stock, Stock Unit, Performance Share, Performance Unit, Incentive Bonus, Other Stock Award or Other Cash Award shall be granted as a Code Section 162(m) Award. Such an Award must comply with the following additional requirements, which shall control over any other provision that pertains to such Award.

14.2 Performance Measures.

(a) Each Code Section 162(m) Award shall be based upon the attainment of specified levels of pre-established, objective Performance Measures that are intended to satisfy the performance based compensation exemption requirements of Code Section 162(m) and the regulations promulgated thereunder. Further, at the discretion of the Committee, an Award also may be subject to goals and restrictions in addition to the Performance Measures.

(b) "Performance Measures" means the measures of performance of the Company and its Subsidiaries used to determine a Participant's entitlement to an Award under the Plan. Such performance measures shall have the same meanings as used in the Company's financial statements, or, if such terms are not used in the Company's financial statements, they shall have the meanings applied pursuant to generally accepted accounting principles, or as used generally in the Company's industry. Performance Measures shall be calculated with respect to the Company and each Subsidiary consolidated therewith for financial reporting purposes or such division or other business unit as may be selected by the Committee. For purposes of the Plan, the Performance Measures shall be calculated in accordance with generally accepted accounting principles to the extent applicable, but, unless otherwise determined by the Committee, prior to the accrual or payment of any Award under this Plan for the same performance period and excluding the effect (whether positive or negative) of any change in accounting standards or any extraordinary, unusual or nonrecurring item, as determined by the Committee, occurring after the establishment of the performance goals. Performance Measures shall be based on one or more of the criteria set forth in Exhibit A which is hereby incorporated by reference, as determined by the Committee.

(c) For each Code Section 162(m) Award, the Committee shall (i) select the Participant who shall be eligible to receive a Code Section 162(m) Award, (ii) determine the applicable performance period, (iii) determine the target levels of the Company or Subsidiary Performance Measures, and (iv) determine the number of shares of Common Stock or cash or other property (or combination thereof) subject to an Award to be paid to each selected Participant. The Committee shall make the foregoing determinations prior to the commencement of services to which an Award relates (or within the permissible time period established under Code Section 162(m)) and while the outcome of the performance goals and targets is uncertain.

14.3 Attainment of Code Section 162(m) Goals.

(a) After each performance period, the Committee shall certify in writing (which may include the written minutes for any meeting of the Committee): (i) if the Company has attained the performance targets, and (ii) the number of shares pursuant to the Award that are to become freely transferable, if applicable, or the cash or other property payable under the Award. The Committee shall have no discretion to waive all or part of the conditions, goals and restrictions applicable to the receipt of full or partial payment of an Award except in the case of a Change in Control of the Corporation or the death or Disability of a Participant.

(b) Notwithstanding the foregoing, the Committee may, in its discretion, reduce any Award based on such factors as may be determined by the Committee, including, without limitation, a determination by the Committee that such a reduction is appropriate in light of pay practices of competitors, or the performance of the Company, a Subsidiary or a Participant relative to the performance of competitors, or performance with respect to the Company's strategic business goals.

14.4 Individual Participant Limitations. Subject to adjustment as provided in Section 4.2, with respect to Awards intended to be Code Section 162(m) Awards and Stock Option and Stock Appreciation Rights Awards intended to be exempt from the deductibility limitation in Code Section 162(m), no Participant in any one fiscal year of the Company may be granted (a) Stock Options or Stock Appreciation Rights with respect to more than 2,500,000 shares of Common Stock in the aggregate; and (b) Restricted Stock, Stock Units, Performance Shares Awards, Incentive Bonus Awards and Other Stock Based Awards that are denominated in shares of Common Stock with respect to more than 2,500,000 shares in the aggregate. The maximum dollar value payable to any Participant in any one (1) fiscal year of the Company with respect to Stock Units, Performance Units or Incentive Bonus Awards or Other Stock-Based Awards that may be settled in cash or other property (other than Common Stock) is $2,500,000. If an Award is cancelled, the cancelled Award shall continue to be counted towards the applicable limitations.

15. Change in Control

15.1 Effect of Change in Control.

(a) The Committee may, at the time of the grant of an Award and as set forth in an Award Agreement, provide for the effect of a "Change in Control" on an Award. Such provisions may include any one or more of the following: (i) the acceleration or extension of time periods for purposes of exercising, vesting in, or realizing gain from any Award, (ii) the elimination or modification of performance or other conditions related to the payment or other rights under an Award, (iii) provision for the cash settlement of an Award for an equivalent cash value, as determined by the Committee, or (iv) such other modification or adjustment to an Award as the Committee deems appropriate to maintain and protect the rights and interests of Participants upon or following a Change in Control. To the extent necessary for compliance with Section 409A of the Code, an Award Agreement shall provide that an Award subject to the requirements of Section 409A that would otherwise become payable upon a Change in Control shall only become payable to the extent that the requirements for a "change in control" for purposes of Section 409A have been satisfied.

(b) Notwithstanding anything to the contrary set forth in the Plan, unless otherwise provided by an Award Agreement, upon or in anticipation of any Change in Control, the Committee may, in its sole and absolute discretion and without the need for the consent of any Participant, take one or more of the following actions contingent upon the occurrence of that Change in Control: (i) cause any or all outstanding Stock Options and Stock Appreciation Rights held by Participants affected by the Change in Control to become vested and immediately exercisable, in whole or in part; (ii) cause any or all outstanding Restricted Stock, Stock Units, Performance Shares, Performance Units, Incentive Bonus Award and any other Award held by Participants affected by the Change in Control to become non-forfeitable, in whole or in part; (iii) cancel any Stock Option or Stock Appreciation Right in exchange for a substitute option in a manner consistent with the requirements of Treasury Regulation. §1.424-1(a) (notwithstanding the fact that the original Stock Option may never have been intended to satisfy the requirements for treatment as an Incentive Stock Option); (iv) cancel any Restricted Stock, Stock Units, Performance Shares or Performance Units held by a Participant in exchange for restricted stock or performance shares of or stock or performance units in respect of the capital stock of any successor corporation; (v) redeem any Restricted Stock held by a Participant affected by the Change in Control for cash and/or other substitute consideration with a value equal to the Fair Market Value of an unrestricted share of Common Stock on the date of the Change in Control; (vi) cancel any Stock Option or Stock Appreciation Right held by a Participant affected by the Change in Control in exchange for cash and/or other substitute consideration with a value equal to (A) the number of shares of Common Stock subject to that Stock Option or Stock Appreciation Right, multiplied by (B) the difference, if any, between the Fair Market Value per share of Common Stock on the date of the Change in Control and the exercise price of that Stock Option or Stock Appreciation Right; *provided,* that if the Fair Market Value per share of Common Stock on the date of the Change in Control does not exceed the exercise price of any such Stock Option or Stock Appreciation Right, the Committee may cancel that Stock Option or Stock Appreciation Right without any payment of consideration therefor; (vii) 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 (provided that such cancelation and exchange does not violate Section 409A of the Code); or (ix) make such other modifications, adjustments or amendments to outstanding Awards or this Plan as the Committee deems necessary or appropriate.

16. General Provisions

16.1 Award Agreement. To the extent deemed necessary by the Committee, an Award under the Plan shall be evidenced by an Award Agreement in a written or electronic form approved by the Committee setting forth the number of shares of Common Stock or units subject to the Award, the exercise price, base price, or purchase price of the Award, the time or times at which an Award will become vested, exercisable or payable and the term of the Award. The Award Agreement may also set forth the effect on an Award of termination of Service under certain circumstances. The Award Agreement shall be subject to and incorporate, by reference or otherwise, all of the applicable terms and conditions of the Plan, and may also set forth other terms and conditions applicable to the Award as determined by the Committee consistent with the limitations of the Plan. Award Agreements evidencing Incentive Stock Options shall contain such terms and conditions as may be necessary to meet the applicable provisions of Section 422 of the Code. The grant of an Award under the Plan shall not confer any rights upon the Participant holding such Award other than such terms, and subject to such conditions, as are specified in the Plan as being applicable to such type of Award (or to all Awards) or as are expressly set forth in the Award Agreement.

16.2 Forfeiture Events/Representations. The Committee may specify in an Award Agreement at the time of the Award that the Participant's rights, payments and benefits with respect to an Award shall be subject to reduction, cancellation, forfeiture or recoupment upon the occurrence of certain specified events, in addition to any otherwise applicable vesting or performance conditions of an Award. Such events shall include, but shall not be limited to, termination of Service for Cause, violation of material Company policies, breach of noncompetition, confidentiality or other restrictive covenants that may apply to the Participant, or other conduct by the Participant that is detrimental to the business or reputation of the Company. The Committee may also specify in an Award Agreement that the Participant's rights, payments and benefits with respect to an Award shall be conditioned upon the Participant making a representation regarding compliance with noncompetition, confidentiality or other restrictive covenants that may apply to the Participant and providing that the Participant's rights, payments and benefits with respect to an Award shall be subject to reduction, cancellation, forfeiture or recoupment on account of a breach of such representation. In addition and without limitation of the foregoing, any amounts paid hereunder shall be subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any "clawback" policy adopted by the Company or as is otherwise required by applicable law or stock exchange listing condition.

16.3 No Assignment or Transfer; Beneficiaries.

(a) Awards under the Plan shall not be assignable or transferable by the Participant, except by will or by the laws of descent and distribution, and shall not be subject in any manner to assignment, alienation, pledge, encumbrance or charge. Notwithstanding the foregoing, the Committee may provide in an Award Agreement that the Participant shall have the right to designate a beneficiary or beneficiaries who shall be entitled to any rights, payments or other benefits specified under an Award following the Participant's death. During the lifetime of a Participant, an Award shall be exercised only by such Participant or such Participant's guardian or legal representative. In the event of a Participant's death, an Award may, to the extent permitted by the Award Agreement, be exercised by the Participant's beneficiary as designated by the Participant in the manner prescribed by the Committee or, in the absence of an authorized beneficiary designation, by the legatee of such Award under the Participant's will or by the Participant's estate in accordance with the Participant's will or the laws of descent and distribution, in each case in the same manner and to the same extent that such Award was exercisable by the Participant on the date of the Participant's death.

(b) Limited Transferability Rights. Notwithstanding anything else in this Section 16.3 to the contrary, the Committee may in its discretion provide in an Award Agreement that an Award in the form of a Nonqualified Stock Option, share-settled Stock Appreciation Right, Restricted Stock, Performance Share or share-settled Other Stock-Based Award may be transferred, on such terms and conditions as the Committee deems appropriate, either (i) by instrument to the Participant's "Immediate Family" (as defined below), (ii) 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 (iii) by gift to charitable institutions. Any transferee of the Participant's rights shall succeed and be subject to all of the terms of the applicable Award Agreement and the Plan. "Immediate Family" means any child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, and shall include adoptive relationships.

16.4 Rights as Stockholder. A Participant shall have no rights as a holder of shares of Common Stock with respect to any unissued securities covered by an Award until the date the Participant becomes the holder of record of such securities. Except as provided in Section 4.2 hereof, no adjustment or other provision shall be made for dividends or other stockholder rights, except to the extent that the Award Agreement provides for dividend payments or dividend equivalent rights.

16.5 Employment or Service. Nothing in the Plan, in the grant of any Award or in any Award Agreement shall confer upon any Eligible Person or Participant any right to continue in the Service of the Company or any of its Subsidiaries, or interfere in any way with the right of the Company or any of its Subsidiaries to terminate the employment or other service relationship of an Eligible Person or Participant for any reason at any time.

16.6 Fractional Shares. In the case of any fractional share or unit resulting from the grant, vesting, payment or crediting of dividends or dividend equivalents under an Award, the Committee shall have the discretionary authority to (i) disregard such fractional share or unit, (ii) round such fractional share or unit to the nearest lower or higher whole share or unit, or (iii) convert such fractional share or unit into a right to receive a cash payment.

16.7 Other Compensation and Benefit Plans. The amount of any compensation deemed to be received by a Participant pursuant to an Award shall not constitute includable compensation for purposes of determining the amount of benefits to which a Participant is entitled under any other compensation or benefit plan or program of the Company or any Subsidiary, including, without limitation, under any bonus, pension, profit-sharing, life insurance, salary continuation or severance benefits plan, except to the extent specifically provided by the terms of any such plan.

16.8 Plan Binding on Transferees. The Plan shall be binding upon the Company, its transferees and assigns, and the Participant, the Participant's executor, administrator and permitted transferees and beneficiaries. In addition, all obligations of the Company under this Plan with respect to Awards granted hereunder shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

16.9 Foreign Jurisdictions. The Committee may adopt, amend and terminate such arrangements and grant such Awards, not inconsistent with the intent of the Plan, as it may deem necessary or desirable to comply with any tax, securities, regulatory or other laws of other jurisdictions with respect to Awards that may be subject to such laws. The terms and conditions of such Awards may vary from the terms and conditions that would otherwise be required by the Plan solely to the extent the Committee deems necessary for such purpose. Moreover, the Board may approve such supplements to or amendments, restatements or alternative versions of the Plan, not inconsistent with the intent of the Plan, as it may consider necessary or appropriate for such purposes, without thereby affecting the terms of the Plan as in effect for any other purpose.

16.10 Substitute Awards in Corporate Transactions. Nothing contained in the Plan shall be construed to limit the right of the Committee to grant Awards under the Plan in connection with the acquisition, whether by purchase, merger, consolidation or other corporate transaction, of the business or assets of any corporation or other entity. Without limiting the foregoing, the Committee may grant Awards under the Plan to an employee or director of another corporation who becomes an Eligible Person by reason of any such corporate transaction in substitution for awards previously granted by such corporation or entity to such person. The terms and conditions of the substitute Awards may vary from the terms and conditions that would otherwise be required by the Plan solely to the extent the Committee deems necessary for such purpose. Any shares of Common Stock subject to these substitute Awards shall not be counted against any of the maximum share limitations set forth in the Plan.

16.11 Stockholder Agreements; Restrictions. Upon the grant of any Award or the distribution of Common Stock pursuant to any Award (as applicable), the Participant (or legal representative) may be required to become a party to a Stockholders Agreement and/or related agreement(s), which shall include such terms and conditions (including without limitation, call rights, drag-along rights and refusal rights), as may be determined by the Committee in its sole discretion.

17. Legal Compliance

17.1 Securities Laws. No shares of Common Stock will be issued or transferred pursuant to an Award unless and until all then applicable requirements imposed by Federal and state securities and other laws, rules and regulations and by any regulatory agencies having jurisdiction, and by any exchanges upon which the shares of Common Stock may be listed, have been fully met. As a condition precedent to the issuance of shares pursuant to the grant or exercise of an Award, the Company may require the Participant to take any reasonable action to meet such requirements. The Committee may impose such conditions on any shares of Common Stock issuable under the Plan as it may deem advisable, including, without limitation, restrictions under the Securities Act, as amended, under the requirements of any exchange upon which such shares of the same class are then listed, and under any blue sky or other securities laws applicable to such shares. The Committee may also require the Participant to represent and warrant at the time of issuance or transfer that the shares of Common Stock are being acquired only for investment purposes and without any current intention to sell or distribute such shares. All Common Stock issued pursuant to the terms of this Plan shall constitute "restricted securities," as that term is defined in Rule 144 promulgated pursuant to the Securities Act, and may not be transferred except in compliance herewith and with the registration requirements of the Securities Act or an exemption therefrom. Certificates representing Common Stock acquired pursuant to an Award may bear such legend as the Company may consider appropriate under the circumstances. If an Award is made to an Eligible Person who is subject to Chinese jurisdiction, and approval of the Award by China's State Administration of Foreign Exchange is needed, the Award may be converted to cash or other equivalent amount if and to the extent that such approval is not obtained.

17.2 Incentive Arrangement. The Plan is designed to provide an on-going, pecuniary incentive for Participants to produce their best efforts to increase the value of the Company. The Plan is not intended to provide retirement income or to defer the receipt of payments hereunder to the termination of a Participant's employment or beyond. The Plan is thus intended not to be a pension or welfare benefit plan that is subject to Employee Retirement Income Security Act of 1974 ("ERISA"), and shall be construed accordingly. All interpretations and determinations hereunder shall be made on a basis consistent with the Plan's status as not an employee benefit plan subject to ERISA.

17.3 Unfunded Plan. The adoption of the Plan and any reservation of shares of Common Stock or cash amounts by the Company to discharge its obligations hereunder shall not be deemed to create a trust or other funded arrangement. Except upon the issuance of Common Stock pursuant to an Award, any rights of a Participant under the Plan shall be those of a general unsecured creditor of the Company, and neither a Participant nor the Participant's permitted transferees or estate shall have any other interest in any assets of the Company by virtue of the Plan. Notwithstanding the foregoing, the Company shall have the right to implement or set aside funds in a grantor trust, subject to the claims of the Company's creditors or otherwise, to discharge its obligations under the Plan.

17.4 Section 409A Compliance. To the extent applicable, it is intended that the Plan and all Awards hereunder comply with the requirements of Section 409A of the Code, and the Plan and all Award Agreements shall be interpreted and applied by the Committee in a manner consistent with this intent in order to avoid the imposition of any additional tax under Section 409A of the Code. In the event that any provision of the Plan or an Award Agreement is determined by the Committee to not comply with the applicable requirements of Section 409A of the Code, the Committee shall have the authority to take such actions and to make such interpretations or changes to the Plan or an Award Agreement as the Committee deems necessary to comply with such requirements, provided that the Committee shall act in a manner that is intended to preserve the economic value of the Award to the Participant. In no event whatsoever shall the Company be liable for any additional tax, interest or penalties that may be imposed on any Participant by Section 409A of the Code or any damages for failing to comply with Section 409A of the Code. Notwithstanding anything in the Plan to the contrary, all or part of an Award payment to a Participant who is determined to constitute a Code Section 409A "Specified Employee" at the time of separation from service, shall be delayed (if then required) under Code Section 409A, and paid in an aggregated lump on the first business day after six (6) months have lapsed following the Participant's separation from service, or the date of the Participant's death, if earlier. Any remaining payments shall be paid on their regularly scheduled payment dates. For purposes of the Plan and any Agreements issued under the Plan, the phrases "separation from service," "termination of employment" and "employment termination" shall be deemed to mean "separation from service" as defined by Code Section 409A and regulations thereunder.

17.5 Tax Withholding.

(a) The Company shall have the power and the 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 regulation to be withheld with respect to any taxable event arising as a result of this Plan, but in no event shall such deduction or withholding or remittance exceed the minimum statutory withholding requirements. Notwithstanding the foregoing, if a minimum statutory amount of withholding does not apply under the laws of any foreign jurisdiction, the Company may withhold such amount for remittance to the applicable taxing authority of such jurisdiction as the Company determines in its discretion, uniformly applied, to be appropriate.

(b) A Participant may, in order to fulfill the withholding obligation, tender previously-acquired shares of Common Stock or have shares of stock withheld from the exercise, provided that the shares have an aggregate Fair Market Value sufficient to satisfy in whole or in part the applicable withholding taxes. The broker-assisted exercise procedure described in Section 6.5 may also be utilized to satisfy the withholding requirements related to the exercise of a Stock Option.

(c) Notwithstanding the foregoing, a Participant may not use shares of Common Stock to satisfy the withholding requirements to the extent that (i) there is a substantial likelihood that the use of such form of payment or the timing of such form of payment would subject the Participant to a substantial risk of liability under Section 16 of the Exchange Act; or (ii) such withholding would constitute a violation of the provisions of any law or regulation (including the Sarbanes-Oxley Act of 2002).

17.6 No Guarantee of Tax Consequences. Neither the Company, the Board, the Committee nor any other Person make any commitment or guarantee that any federal, state, local or foreign tax treatment will apply or be available to any Participant or any other person hereunder.

17.7 Severability. If any provision of the Plan or any Award Agreement shall be determined to be illegal or unenforceable by any court of law in any jurisdiction, the remaining provisions hereof and thereof shall be severable and enforceable in accordance with their terms, and all provisions shall remain enforceable in any other jurisdiction.

17.8 Stock Certificates; Book Entry Form. Notwithstanding any provision of the Plan to the contrary, unless otherwise determined by the Committee or required by any applicable law, rule or regulation, any obligation set forth in the Plan pertaining to the delivery or issuance of stock certificates evidencing shares of Common Stock may be satisfied by having issuance and/or ownership of such shares recorded on the books and records of the Company (or, as applicable, its transfer agent or stock plan administrator).

17.9 Governing Law. The Plan and all rights hereunder shall be subject to and interpreted in accordance with the laws of the State of New Jersey, without reference to the principles of conflicts of laws, and to applicable Federal securities laws.

18. Effective Date, Amendment and Termination

18.1 Effective Date. The effective date of the Plan shall be the date on which the Plan is approved by the requisite percentage of the holders of the Common Stock of the Company; provided, however, that Awards granted under the Plan subsequent to the approval of the Plan by the Board shall be valid if such stockholder approval occurs within one year of the date on which such Board approval occurs.

18.2 Amendment; Termination. The Board may suspend or terminate the Plan (or any portion thereof) at any time and may amend the Plan at any time and from time to time in such respects as the Board may deem advisable or in the best interests of the Company or any Subsidiary; provided, however, that (a) no such amendment, suspension or termination shall materially and adversely affect the rights of any Participant under any outstanding Awards, without the consent of such Participant, (b) to the extent necessary and desirable to comply with any applicable law, regulation, or stock exchange rule, the Company shall obtain stockholder approval of any Plan amendment in such a manner and to such a degree as required, and (c) stockholder approval is required for any amendment to the Plan that (i) increases the number of shares of Common Stock available for issuance under the Plan, or (ii) changes the persons or class of persons eligible to receive Awards. The Plan will continue in effect until terminated in accordance with this Section 18.2; *provided, however,* that no Award will be granted hereunder on or after the 10th anniversary of the date of the Plan's initial adoption by the Board; *but provided further,* that Awards granted prior to such 10th anniversary may extend beyond that date.

BOARD APPROVAL OF PLAN AS AMENDED AND RESTATED: 05/08/2014

STOCKHOLDER APPROVAL OF PLAN AS AMENDED AND RESTATED: 06/16/2014

EXHIBIT A

PERFORMANCE MEASURES

Code Section 162(m) Awards shall be based on the attainment of objective performance goals that are established by the Committee and relate to one or more Performance Measures, in each case on specified date or over any period, up to 10 years, as determined by the Committee.

"Performance Measures" means the following business criteria (or any combination thereof) with respect to one or more of the Company, any Subsidiary or any division or operating unit thereof:

- pre-tax income,
- after-tax income,
- net income (meaning net income as reflected in the Company's financial reports for the applicable period, on an aggregate, diluted and/or per share basis, or economic net income),
- operating income or profit,
- cash flow, free cash flow, cash flow return on investment (discounted or otherwise), net cash provided by operations, or cash flow in excess of cost of capital,
- earnings per share (basic or diluted),
- return on equity,
- returns on sales or revenues,
- return on invested capital or assets (gross or net),
- cash, funds or earnings available for distribution,
- appreciation in the fair market value of the Common Stock,
- operating expenses,
- implementation or completion of critical projects or processes,
- return on investment,
- total return to stockholders (meaning the aggregate Common Stock price appreciation and
- dividends paid (assuming full reinvestment of dividends) during the applicable period),
- net earnings growth,
- stock appreciation (meaning an increase in the price or value of the Common Stock after the date of grant of an award and during the applicable period),
- related return ratios,
- increase in revenues,

- the Company's published ranking against its peer group of real estate investment trusts based on total stockholder return,

- net earnings,

- changes (or the absence of changes) in the per share or aggregate market price of the Company's Common Stock,

- number of securities sold,

- 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,

- total revenue growth (meaning the increase in total revenues after the date of grant of an award and during the applicable period, as reflected in the Company's financial reports for the applicable period),

- economic value created,

- operating margin or profit margin,

- Share price or total shareholder return,

- cost targets, reductions and savings, productivity and efficiencies,

- strategic business criteria, consisting of one or more objectives based on meeting objectively determinable 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,

- objectively determinable personal professional objectives, including any of the foregoing 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

- any combination of, or a specified increase or improvement in, any of the foregoing.

Where applicable, the Performance Measures may be expressed in terms of attaining a specified level of the particular criteria or the attainment of a percentage increase or decrease in the particular criteria, and may be applied to one or more of the Company, a Subsidiary or affiliate, or a division or strategic business unit of the Company, or may be applied to the performance of the Company relative to a market index, a group of other companies or a combination thereof, all as determined by the Committee.

The Performance Measures may include a threshold level of performance below which no payment shall be made (or no vesting shall occur), levels of performance at which specified payments shall be made (or specified vesting shall occur), and a maximum level of performance above which no additional payment shall be made (or at which full vesting shall occur).

Except as otherwise expressly provided, all financial terms are used as defined under Generally Accepted Accounting Principles ("GAAP") and all determinations shall be made in accordance with GAAP, as applied by the Company in the preparation of its periodic reports to stockholders.

To the extent permitted by Section 162(m) of the Code, unless the Committee provides otherwise at the time of establishing the performance goals, for each fiscal year of the Company, the Committee shall have the authority to make equitable adjustments to the Performance Measures in recognition of unusual or non-recurring events affecting the Company or any Subsidiary or affiliate or the financial statements of the Company or any Subsidiary or affiliate and may provide for objectively determinable adjustments, as determined in accordance with GAAP, to any of the Performance Measures described above for one or more of the items of gain, loss, profit or expense: (A) determined to be extraordinary or unusual in nature or infrequent in occurrence, (B) related to the disposal of a segment of a business, (C) related to a change in accounting principle under GAAP or a change in applicable laws or regulations, (D) related to discontinued operations that do not qualify as a segment of a business under GAAP, and (E) attributable to the business operations of any entity acquired by the Company during the fiscal year.

Exhibit 10.18

[*Confidential Treatment has been requested as to certain portions of this document. Each such portion, which has been omitted herein and replaced with an asterisk [*], has been filed separately with the Securities and Exchange Commission.]

AMENDED AND RESTATED

EXCLUSIVE LICENSE AGREEMENT

BETWEEN

RUTGERS, THE STATE UNIVERSITY OF NEW JERSEY

AND

AQUARIUS BIOTECHNOLOGIES INC.

EFFECTIVE JANUARY 29, 2015

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This Amended and Restated Exclusive License Agreement (hereinafter the "AGREEMENT") is made and is effective as of the 29th day of January, 2015, (hereinafter the “RESTATEMENT DATE”) by and between Rutgers, The State University of New Jersey, having its statewide Office of Technology Commercialization at ASB Annex III, 3 Rutgers Plaza, New Brunswick, New Jersey 08901-8559, (hereinafter the “LICENSOR”) and Aquarius Biotechnologies Inc., a corporation organized and existing under the laws of Delaware (hereinafter the "LICENSEE") having a place of business at 2037 W. Carroll Avenue, Chicago, IL 60612. Each of LICENSOR and LICENSEE shall be referred to herein as a “PARTY” and collectively, as the “PARTIES.”

RECITALS

WHEREAS, certain PATENT RIGHTS were acquired in the course of research at LICENSOR by the inventors of the applications and patents listed in Appendix A (hereinafter the INVENTOR(S)) and are owned by LICENSOR; and,

WHEREAS, LICENSOR owns the PATENT RIGHTS described in Section 1.12 below and owns or controls related TECHNICAL INFORMATION defined in Section 1.13 below; and,

WHEREAS, LICENSEE desires to secure licenses to use, develop, manufacture, market and commercially exploit the PATENT RIGHTS and TECHNICAL INFORMATION; and,

WHEREAS, LICENSOR desires that the PATENT RIGHTS and TECHNICAL INFORMATION be developed and utilized to the fullest extent possible so that the benefits can be enjoyed by the general public;

WHEREAS, the University of Medicine and Dentistry of New Jersey, as licensor, and Aquarius Biotechnologies had previously entered into that certain Exclusive License Agreement, effective as of March 25, 2013 (the “Original License Agreement”); and

WHEREAS, on or about July 1, 2013 the University of Medicine and Dentistry merged with and into Rutgers, The State University of New Jersey; and

WHEREAS, the PARTIES wish to replace the Original License Agreement in its entirety with this AGREEMENT as of the RESTATEMENT DATE;

NOW THEREFORE, in consideration of the premises and of the promises and covenants contained herein and intending to be legally bound hereby, the parties agree as follows:

ARTICLE 1 – DEFINITIONS

1.1 AFFILIATE means, when used with reference to LICENSEE, any ENTITY directly or indirectly controlling, controlled by or under common control with LICENSEE. For purposes of this AGREEMENT, "control" means the direct or indirect ownership of over fifty percent (50%) of the outstanding voting securities of an ENTITY or the right to receive over fifty percent (50%) of the profits or earnings of an ENTITY, directly or indirectly.

1.2 BANKRUPTCY EVENT means that the ENTITY in question becomes insolvent, or voluntary or involuntary proceedings by or against such ENTITY are instituted in bankruptcy or under any insolvency law, or a receiver or custodian is appointed for such ENTITY, or proceedings are instituted by or against such ENTITY for corporate reorganization or the dissolution of such ENTITY, which proceedings, if voluntary, shall not have been dismissed within sixty (60) days after the date of filing, or such ENTITY makes an assignment for the benefit of creditors, or substantially all of the assets of such ENTITY are seized or attached and not released within sixty (60) days thereafter.

1.3 CALENDAR QUARTER means each three (3) month period, or any portion thereof, beginning on January 1, April 1, July 1 and October 1.

1.4 CALENDAR YEAR means a period of twelve (12) months beginning on January 1 and ending on December 31.

1.5 CHANGE OF CONTROL means the sale of all or substantially all the assets of a Party; any merger, consolidation or acquisition of a Party with, by or into another corporation, entity or person; or any change in the ownership of more than fifty percent (50%) of the voting capital stock of a Party in one or more related transactions.

1.6 CONFIDENTIAL INFORMATION means and includes (i) all TECHNICAL INFORMATION (as defined below) and (ii) all other information including reports that relate to a PARTY in the course of this AGREEMENT, including without limitation, management reports, financial statements, internal memoranda, marketing plans, financial, development or marketing reports and other materials of a proprietary nature, owned or controlled by a PARTY and identified as confidential or proprietary at the time delivered or communicated to the other PARTY within thirty (30) days thereafter.

1.7 ENTITY means a corporation or other business entity.

1.8 FEDERAL GOVERNMENT INTEREST means the rights of the United States Government under Public Laws 96-517, 97-256 and 98-620, codified at 35 U.S.C. 200-212, and any regulations issued there under; as such statutes and regulations may be amended from time to time during the term of this Agreement.

1.9 FAIR MARKET VALUE means (i) in the case of a SALE, the cash consideration that LICENSEE, its AFFILIATE or sublicensee, as the case may be, would realize from an unaffiliated, unrelated buyer in an arm's length SALE of an identical LICENSED PRODUCT sold in the same quantity and at the same time and place of the transaction, or (ii) in the case of a transaction other than a sale, the current value to LICENSEE or its AFFILIATES of consideration they receive in such transaction, as determined by the parties, or by a neutral third party appraiser selected by LICENSOR if the parties are unable to agree within thirty (30) days of commencing discussions.

1.10 FIELD OR FIELD OF USE means all fields.

1.11 NET SALES means, with respect to any SALE of a LICENSED PRODUCT, the greater of (i) the gross consideration charged for the LICENSED PRODUCT by LICENSEE, its AFFILIATES or their sublicensees (regardless of tier), in an arm's-length transaction or (ii) the gross consideration received or agreed to be received by LICENSEE, its AFFILIATES or their sublicensees (regardless of tier) on account of the SALE in any arm's-length transaction to an unrelated third party, in each case (i) and (ii) less documented qualifying costs borne by the seller that were directly attributable to the SALE and identified on the invoice. For clarity, in the case of any SALE of a LICENSED PRODUCT between or among LICENSEE, its AFFILIATES or their sublicensees (regardless of tier) which are intended for resale to an unaffiliated third party, no NET SALES shall apply; in such circumstance, NET SALES shall be calculated as above only on the consideration charged to or received from the unaffiliated third party.

1.11.1 Qualifying costs under Section 1.11 shall include the following:

(i) Cash, trade or quantity discounts customary in the trade;
(ii) Reasonable credits or refunds for claims or returns, not exceeding the original invoice amount less all qualifying costs;
(iii) Prepaid outbound transportation insurance premiums;
(iv) Prepaid outbound transportation expenses; and
(v) Sales and use taxes imposed by a governmental agency.

1.12 LICENSED PRODUCT(S) means any product, material, kit, service, process or procedure whose discovery, development, registration, manufacture, use or sale would be covered in whole or in part by at least one VALID CLAIM of the PATENT RIGHTS and/or has utilized or would utilize TECHNICAL INFORMATION.

1.13 PATENT RIGHTS means the following, to the extent that they are owned by LICENSOR and included in this Agreement at LICENSEE's election: (a) the patents and patent applications listed in Appendix A (hereafter referred to as "Patent Applications"), (b) any patents issuing on any such Patent Applications, (c) all foreign patents and patent applications corresponding to all of the foregoing (including PCT filings) and (d) all reissues, extensions (including governmental equivalents thereto), substitutions, continuations, continuations-in-part (but only to the extent their claims have the same priority date, subject matter and inventors as their parent application) and divisionals thereof.

1.14 TECHNICAL INFORMATION means any unpublished research and development information, unpatented inventions, know-how, trade secrets, and technical information, technical data and other information and materials related to inventions listed in Appendix A, and which information is not otherwise publicly known, that are (a) necessary or useful to discover, develop, make, have made, use or sell a LICENSED PRODUCT(S), (b) owned or controlled by LICENSOR and came into LICENSOR's possession prior to the RESTATEMENT DATE, (c) developed by or under the supervision of one or more of the INVENTOR(S) of the PATENT RIGHTS prior to the RESTATEMENT DATE, and (d) can be freely licensed to others by LICENSOR without incurring third party obligations (except for certain possible royalty obligations by LICENSOR to BDSI if BDSI know-how is licensed), Examples of such TECHNICAL INFORMATION include, but are not limited to the following (i) research and development information as described in laboratory notebooks of Dr. Raphael Mannino and Ruying Lu, to the extent such laboratory notebooks were created while each was an employee of LICENSOR; (ii) CONFIDENTIAL INFORMATION, except such CONFIDENTIAL INFORMATION which falls under any exception described in Sections 7.1.1 through 7.1.3; (iv) research and development information formerly of BDSI, transferred to LICENSOR and presently owned by LICENSOR, and referred to as BDSI KNOW-HOW and BDSI CONFIDENTIAL INFORMATION in that certain UMDNJ/BDSI Agreement, dated June 30, 2012; (v) know-how and trade secrets that are in Dr. Mannino's possession as of the RESTATEMENT DATE and under the LICENSOR'S patent policy are considered to be the property of LICENSOR; (vi) know-how and trade secrets that were in Ruying Lu's possession as of the last date of her employment by LICENSOR and under the LICENSOR'S patent policy are considered to be the property of LICENSOR; and (vii) all information assigned by BDSI to LICENSOR, both written and electronic, pertaining to the development, submission and performance of an IND application, PIND **[*]**, Product Name: **[*]** Cochleate Amphotericin B (CAMB), including but not limited to all manufacturing and batch records related to the manufacturing of the GMP **[*]** Cochleate Amphotericin B product by **[*]** and all clinical trial information and data relating to the Phase 1a, single escalating dose, human clinical trial, performed by **[*]**, only to the extent such information was actually provided by LICENSOR to LICENSEE.

1.15 SALE means any bona fide, arm's-length transaction for which consideration is received or expected for the sale, use, lease, transfer or other disposition of LICENSED PRODUCT(S). A SALE of LICENSED PRODUCT(S) shall be deemed completed at the time LICENSEE, its AFFILIATE or a sublicensee, as the case may be, contracts for, invoices, ships, or receives payment for such LICENSED PRODUCT(S) from a third party unaffiliated with LICENSEE, its AFFILIATES and the applicable sublicensee, whichever occurs first. If a particular individual item of LICENSED PRODUCT is sold by more than one of LICENSEE, an AFFILIATE, or a sublicensee, the sale at highest price (after deducting qualifying costs) shall be the sale considered for purposes of determining NET SALES.

1.16 TERRITORY means worldwide.

1.17 VALID CLAIM means (i) an issued and unexpired claim within the PATENT RIGHTS or (ii) for pending patent applications within the PATENT RIGHTS a claim of such pending patent application that was filed in good faith, has not been pending for more than seven (7) years, and which has not been abandoned or finally disallowed without the possibility of appeal or refilling of such application.

1.18 BDSI means BioDelivery Sciences International, Inc., a former licensee of LICENSOR.

ARTICLE 2 - LICENSE GRANT

2.1 LICENSOR grants to LICENSEE for the term of this AGREEMENT a royalty-bearing right and exclusive license under Table I of the Appendix A (i) of the PATENT RIGHTS, a royalty-bearing right and exclusive license under Table II of the Appendix A (i) of the PATENT RIGHTS to the extent LICENSOR is a co-owner of the identified PATENT RIGHTS, a non-exclusive license under the Appendix A (ii) of the PATENT RIGHTS and non-exclusive license to use the TECHNICAL INFORMATION, with the right to grant sublicenses, to make, have made, use, import, have sold, offer to sell and sell LICENSED PRODUCT(S) in TERRITORY and in the FIELD OF USE. Except for the rights granted in Section 2.1, no other rights or licenses are granted hereunder either expressly or by implication or estoppel. LICENSOR agrees not to grant a commercial license to anyone other than LICENSEE under the Appendix A (ii) of the PATENT RIGHTS, or grant a commercial license to anyone other than LICENSEE to said TECHNICAL INFORMATION, subject to any limitations stated herein, for the duration of this AGREEMENT. LICENSEE may delegate performance of duties and obligations under this AGREEMENT to its AFFILIATE(S), but LICENSEE shall at all times have primary responsibility and liability for the performance of all LICENSEE duties and obligations arising under this AGREEMENT, whether or not so delegated. To the extent that TECHNICAL INFORMATION includes an IND for Amphotericin B developed prior to the RESTATEMENT DATE, LICENSOR shall not license such TECHNICAL INFORMATION to third parties for commercial use except (i) in the event of early termination of this AGREEMENT, or (ii) in **[*]** LICENSEE'S rights in PATENT RIGHTS relating to such TECHNICAL INFORMATION **[*]**, or (iii) in **[*]** **LICENSEE** is not meeting its **[*]** obligations under this AGREEMENT.

2.2 LICENSEE acknowledges that all rights reserved by the U.S. government and/or other sponsors of the research on which the rights licensed hereunder are based, may limit the scope of the license. For example, the United States government retains certain rights in intellectual property funded in whole or part under any contract, grant or similar agreement with a Federal agency. The license grants of Section 2.1 above are expressly subject to all such rights. LICENSOR represents to LICENSEE that, as of the RESTATEMENT DATE and after reasonable inquiry, the Director of the Office of Research Commercialization of LICENSOR does not know of (i) any agreements between LICENSOR and any third parties that conflict with the terms of this AGREEMENT, including but not limited to the grant of rights provided under this Article 2 and (ii) any agreement to which LICENSOR is a party or by which it is bound that restricts the exercise by LICENSEE of the rights granted under this AGREEMENT, including but not limited to the grant of rights provided under this Article 2.

2.3 LICENSOR expressly reserves the right to have the PATENT RIGHTS and TECHNICAL INFORMATION rights licensed hereunder used for educational, non-commercial research and other non-business purposes and to publish the results thereof. Notwithstanding the foregoing, LICENSOR shall provide LICENSEE with the right of review and inspection of any article of writing relating to the PATENT RIGHTS and originating from, under the direction or supervision of Dr. Mannino, and intended for publication not less than sixty (60) days in advance of submission of such article so that LICENSEE may seek appropriate patent protection. LICENSOR may conduct commercial research for LICENSEE pursuant to a mutually acceptable research agreement.

2.4 Some TECHNICAL INFORMATION may have been made available to the public without restriction prior to the EFFECTIVE DATE of the Original Agreement. LICENSOR agrees to use reasonable effort to the extent it has not already done so to deliver to LICENSEE the TECHNICAL INFORMATION upon reasonable request by LICENSEE.

ARTICLE 3- SUBLICENSES

3.1 The right to grant sublicenses conferred upon LICENSEE under this AGREEMENT is subject to the conditions of this Article 3. Copies of all sublicenses shall be provided by LICENSEE to LICENSOR within thirty (30) days after execution.

3.2 Sublicensees may, at LICENSEE's discretion, further sublicense the rights granted to them, subject to the applicable terms and conditions of the license granted to LICENSEE under this AGREEMENT, and subject to the following further conditions: (i) the further sublicensee may not grant further sublicenses without LICENSOR'S consent, which consent will not be unreasonably withheld; (ii) NET SALES and SALES shall include, without limitation, SALES by further sublicensees; (iii) milestones referred to in Section 4.4 reached by further sublicensees shall trigger payment obligations by LICENSEE to LICENSOR; and (iv) consideration received by LICENSEE resulting from further sublicensing shall be included in the calculations under Section 4.5 and 4.5.1. Copies of all sublicenses and further sublicenses by sublicensees shall be provided by LICENSEE to LICENSOR within sixty (60) days after execution.

3.3 The legally controlling language of any sublicense shall be English. LICENSOR'S receipt of any sublicense shall not constitute an approval of such sublicense or a waiver of any of LICENSOR'S rights or LICENSEE'S obligations hereunder.

3.4 Upon termination of this AGREEMENT for any reason, LICENSOR in its sole discretion shall determine whether any or all sublicenses shall be cancelled or assigned to LICENSOR. LICENSOR agrees to negotiate in good faith with sublicensees for a period of no less than 90 days regarding a license of LICENSOR's rights similar to those rights held by such sublicensee prior to such termination.

3.5 Notwithstanding any such sublicense, LICENSEE shall remain primarily liable to LICENSOR for all of the LICENSEE'S duties and obligations contained in this AGREEMENT.

3.6. Except as required by law, LICENSOR agrees to use reasonable efforts, and in no case less effort than LICENSOR uses with respect to its own confidential information, (i) to receive and maintain all information provided by LICENSEE under this Article 3, including but not limited to copies sublicenses and further sublicenses, in strict confidence, except such information which falls under any exception described in Sections 7.1.1 through 7.1.3, and (ii) to not distribute, disclose or disseminate any of the information described in (i) above including but not limited to copies of sublicenses and further sublicenses, to anyone except employees of LICENSOR and others who are bound by obligations of confidentiality to LICENSOR who have a reasonable need to have access to such information, at LICENSOR'S sole discretion.

ARTICLE 4 – FEES, ROYALTIES, ANNUAL AND MILESTONE PAYMENTS, OTHER PAYMENTS AND EQUITY

4.1 As partial consideration, LICENSEE shall pay to LICENSOR a License Issue Fee of twenty-five thousand dollars ($25,000) upon execution of this AGREEMENT.

4.2 LICENSEE shall pay to LICENSOR a royalty as provided in the subsections of this Section 4.2, except under the circumstances described hereafter in Section 4.5.1.

4.2.1 For LICENSED PRODUCTS [*], LICENSEE shall pay to LICENSOR:

(i) for NET SALES in countries where such LICENSED PRODUCT(S) are covered by a VALID CLAIM:

[*]% of NET SALES between $[*] to $[*] in NET SALES,
[*]% of NET SALES between $[*] and up to $[*] in NET SALES,
[*]% of NET SALES beyond $[*]

(ii) for NET SALES during a period of [*] after first commercial sale of such LICENSED PRODUCT(S) in each country where such LICENSED PRODUCT(S) utilize TECHNICAL INFORMATION and are not covered by a VALID CLAIM:

[*]% of NET SALES for $[*] to $[*] in NET SALES,
[*]% of NET SALES above $[*] and up to $[*] in NET SALES,
[*]% of NET SALES for $[*] in NET SALES and beyond

(iii) the above royalties in this Section 4.2.1 shall be [*] in the event LICENSEE must (a) substantially [*] which has been described in the definition of TECHNICAL INFORMATION (Section 1.13) and (b) substantially [*].

(iv) notwithstanding those royalties provided in subsections (i)-(iii) of this Section 4.2.1, if LICENSEE receives royalty revenue based on net sales of LICENSED PRODUCTS [*] from a sublicensee, the amounts due LICENSOR under this Section shall not [*] of such royalty revenue received by LICENSEE from such sublicensee.

4.2.2 For LICENSED PRODUCTS [*], LICENSEE shall pay to LICENSOR,

(i) for NET SALES in countries where such LICENSED PRODUCT(S) are covered by a VALID CLAIM:

[*]% of NET SALES between $[*] and up to $[*] in NET SALES,
[*]% of NET SALES beyond $[*] and up to $[*] in NET SALES,
[*]% of NET SALES beyond $[*]

(ii) for NET SALES during a period of [*] after first commercial sale of such LICENSED PRODUCT(S) in each country where such LICENSED PRODUCTS utilize TECHNICAL INFORMATION and are not covered by the scope of a VALID CLAIM:

[*]% of NET SALES between $[*] and up to $[*] in NET SALES,

[*]% of NET SALES beyond $**[*]** and up to $**[*]** in NET SALES,
[*]% of NET SALES beyond $**[*]**

4.2.3 In the event it becomes necessary, as determined by LICENSEE in its reasonable discretion, for LICENSEE to obtain a license under patent rights of a third party which are necessary in order for LICENSEE to make, have made, use, or sell the LICENSED PRODUCT(S) and LICENSEE must pay such third party a royalty on net sales of LICENSED PRODUCT(S) for such license, upon LICENSEE'S provision of a copy of such license and all related agreements to LICENSOR, notice of such license to LICENSOR, , the royalty rates provided in this Article 4 for any LICENSED PRODUCT(S) will be **[*]** to third parties on such LICENSED PRODUCT(S), provided that in no event shall the royalty rates under any provision of this Article 4 be **[*]** of (i) **[*]** the original royalty rates set forth in Sections 4.2.1 and 4.2.2 above, or (ii) **[*]** percent of Net Sales.

4.2.4 Notwithstanding any other provision of this AGREEMENT, the **[*]** royalty rates will be **[*]** to in this Section 4 shall be the following: (a) for 4.2.1 (i) **[*]**%; (b) for 4.2.1 (ii) **[*]**%; (c) for 4.2.2 (i) **[*]**%; (d) for 4.2.2 (ii) **[*]**%.

4.3 LICENSEE shall pay to LICENSOR on each anniversary of the RESTATEMENT DATE a non-refundable annual license fee as follows. Each of such fees will be creditable against royalties due during the 12 months following the due date for the payment of the annual fee.

PERIOD	
First and second anniversaries:	$ 10,000
Third anniversary:	$ 20,000
Fourth anniversary:	$ 25,000
Fifth anniversary and each Anniversary thereafter	$ 50,000

4.4 For each LICENSED PRODUCT reaching a milestone listed below, LICENSEE shall pay either (y) that amount due under Sections 4.5 or 4.5.1 for that milestone, or (z) the following milestone payments, whichever is **[*]**, within **[*]** after the reaching of each milestone by LICENSEE, its AFFILIATES or its sublicensees, and shall report the reaching of each milestone within sixty (60) days after it is reached.

(i) for each LICENSED PRODUCT(S) **[*]**:

(a) **[*]**;
(b) **[*]**;
(c) **[*]**;
(d) **[*]**.

(ii) for each LICENSED PRODUCT(S) **[*]**:

(a) **[*]**;
(b) **[*]**;
(c) **[*]**;
(d) **[*]**;
(e) **[*]**.

(iii) Sales Milestone fee of one hundred thousand dollars ($100,000) shall be paid by LICENSEE to LICENSOR upon reaching sales of **[*]**.

4.4.1 Notwithstanding anything to the contrary set forth in this AGREEMENT, it shall be understood that the **[*]** contemplated by the LICENSEE as of the RESTATEMENT DATE and to be supported by the **[*]** will not trigger the milestone payment of 4.4(i)(a) or 4.4(ii)(b). This contemplated **[*]** shall be the only exemption allowed by this AGREEMENT, and that all future **[*]** initiated after the execution date of this AGREEMENT shall be subject to the payment terms of this section 4.4. For purposes of this section 4.4 only, it shall be understood that a **[*]** shall mean a **[*];** while a **[*]** shall mean a **[*]**.

4.5 Except under the circumstances described hereafter in this Section 4.5 and in Section 4.5.1, LICENSEE shall pay to LICENSOR **[*]** of all non-royalty consideration (other than (i) cash received for direct costs of research and development personnel working on LICENSED PRODUCTS and spent for such purposes within two years of receipt, (ii) the FAIR MARKET VALUE of machinery and equipment to the extent non-cash consideration used to support research and development activities for LICENSED PRODUCTS within two years of receipt, and (iii) reimbursement of costs incurred by LICENSEE for PATENT RIGHTS) received by LICENSEE from sublicensing or transferring any of the rights licensed to LICENSEE hereunder. All non-cash consideration received by LICENSEE from such sublicensees shall be valued at the FAIR MARKET VALUE as of the date of receipt, and shall be paid to LICENSOR either in cash (U.S. dollars) or in equity in LICENSEE or in another mutually agreeable method, within ninety (90) days after the date of receipt; the parties agree to negotiate in good faith to determine a mutually acceptable and equitable method of resolving this situation should it occur. Beginning on the first anniversary of the Original Agreement EFFECTIVE DATE after LICENSEE has spent at least **[*]** on the direct costs of research and development personnel working on LICENSED PRODUCTS and not reimbursed or paid for by one or more sublicensees, the amount of non-royalty consideration payable to LICENSOR shall be **[*]**. Beginning on the first anniversary of the Original Agreement EFFECTIVE DATE after LICENSEE has spent at least **[*]** on the direct costs of research and development personnel working on LICENSED PRODUCTS and not reimbursed or paid for by one or more sublicensees, the amount of non-royalty consideration payable to LICENSOR shall be **[*]**.

4.5.1 In the event where LICENSEE grants a sublicense of the rights granted hereunder to an unaffiliated third party which **[*]**, then, in lieu of the royalty and non-royalty consideration described in Sections 4.2 and 4.6, LICENSEE shall pay LICENSOR **[*]** received by LICENSEE from sublicensing or transferring any of the rights licensed to LICENSEE hereunder to a third party sublicensee, without the step down described in the last two sentences of Section 4.5.

4.6 Royalties payable pursuant to Section 4.2 hereof and received during a CALENDAR QUARTER and other payments due hereunder pursuant to Sections 4.5 or 10.2 hereof based on recoveries or consideration received during a CALENDAR QUARTER by LICENSEE or its AFFLITIATE(S) shall be paid within forty-five (45) days following the last day of the applicable CALENDAR QUARTER.

4.7 NET SALES of any LICENSED PRODUCT(S) shall not be subject to more than one assessment of the scheduled royalty, and such assessment shall be that which yields the highest royalty payment to LICENSOR.

4.8 All dollar amounts referred to in this AGREEMENT are expressed in United States dollars. All payments to LICENSOR under this AGREEMENT shall be made in United States dollars by check payable to LICESOR.

4.9 If LICENSEE receives revenues from SALES of LICENSED PRODUCT(S) and or sublicense payments pursuant to Section 4.5 in currency other than United States dollars, such revenues shall be converted into United States dollars prior to payment to LICENSOR at the conversion rate for the foreign currency as published in the eastern edition of The Wall Street Journal as of the last business day of the applicable CALENDAR QUARTER. If legal restrictions in a country prevent the acquisition or prompt remittance of United States dollars to LICENSOR with respect to SALES of LICENSED PRODUCTS in such country, LICENSEE shall make timely payment to LICENSOR from LICENSEE's other sources of U.S. dollars.

4.10 LICENSEE shall be responsible for any and all taxes, fees, or other charges imposed by the government of any country outside the United States on the remittance of royalty income for sales of LICENSED PRODUCT occurring in any such country. LICENSEE shall also be responsible for all bank transfer charges.

4.11 In the event that any patent or any claim thereof included within the PATENT RIGHTS shall be held invalid in a final decision by a court of competent jurisdiction and last resort in any country and from which no appeal has or can be taken, all obligation to pay royalties based on such patent or claim or any claim patentably indistinct there from shall cease as of the date of such final decision with respect to such country. LICENSEE shall not, however, be relieved from paying any royalties that accrued before such decision or that are based on (i) another patent or claim not involved in such decision or (ii) TECHNICAL INFORMATION.

4.12 Amounts due LICENSOR under this AGREEMENT that are not paid when due shall accrue interest from the due date until paid, at a rate equal to one and one-half percent (1.5%) per month (or the maximum allowed by law, if less).

4.13 As of the RESTATEMENT DATE, as partial consideration for the license granted under this Agreement, LICENSEE has issued to LICENSOR **[*]** common stock of LICENSEE, which represented five percent (5%) of LICENSEE's equity on a fully diluted basis outstanding on the EFFECTIVE DATE of the Original Agreement. LICENSEE shall **[*]** at such time or times as may be necessary to assure that LICENSOR's **[*]** five percent (5%) **[*]** until one of the following happens: LICENSEE has **[*]** OR the **[*]**. Notwithstanding the foregoing, in the event of a CHANGE OF CONTROL of LICENSEE, immediately in advance of the consummation of such CHANGE OF CONTROL, LICENSEE shall issue to LICENSOR such additional amount of common stock of LICENSEE as may be necessary to bring LICENSOR's total holdings of common stock of LICENSEE to an amount equal to seven and a half percent (7.5%) of the equity of LICENSEE on a fully diluted basis immediately prior to the consummation of such CHANGE OF CONTROL, at which point the anti-dilution provisions of this Section 4.13 shall be considered fully satisfied and of no further force or effect.

4.14 If LICENSEE proposes to **[*]**, then LICENSOR and/or its Assignee (defined below) will have the right to **[*]**. The term "Assignee" means (a) **[*]**, or its assignee, (b) Rutgers University, or its assignee or (c) any entity that is controlled by LICENSOR.

4.15 LICENSOR shall have the right to have an observer seat on the Board of Directors of LICENSEE as long as LICENSOR's common stock in LICENSEE represents more than one percent (1%) of LICENSEE's equity issued and outstanding on a fully-diluted basis; provided, however, notwithstanding LICENSOR's interest in LICENSEE, the right to an observer seat under this Section 4.16 shall cease no later than the listing of LICENSEE's common stock on any public securities exchange in the United States of America. LICENSOR's observer shall be the Executive Director of LICENSOR's Office of Technology Transfer and Business Development, or another designee of LICENSOR, its successors or assigns. LICENSEE shall provide to LICENSOR all notices and information that it provides to its full members of the Board of Directors at the same time it provides it to them. For the avoidance of doubt, LICENSOR's rights under this Section 4.15 shall become null and void should LICENSEE undergo a CHANGE OF CONTROL.

ARTICLE 5- ROYALTY, PROGRESS AND PAYMENT REPORTS

5.1 LICENSOR shall deliver to LICENSEE with each payment made pursuant to Section 4.7 herein a report, certified by the chief financial officer of LICENSEE, setting forth in reasonable detail the calculation of the royalties, as well as all other payments due to LICENSOR during such CALENDAR QUARTER pursuant to the terms of Article 4 of this AGREEMENT. Each report shall include, without limitation:

5.1.1 Number of LICENSED PRODUCT(S) involved in SALES, listed by country;
5.1.2 Gross SALES of LICENSED PRODUCT(S);
5.1.3 Qualifying costs, as defined in Section 1.11, listed by category of cost;
5.1.4 NET SALES of LICENSED PRODUCT(S) listed by country;
5.15 Royalties owed to LICENSOR;
5.1.6 Deductions from royalties owed because of annual fees paid under Section 4.3;
5.1.7 Calculation of LICENSOR'S share of any infringement litigation recoveries subject to payment under Section 4.5 and any sublicense consideration received and subject to payment under Section 4.6.
5.1.8 Listing and accounting for any other payments due to LICENSOR pursuant to Article 4 hereof during the CALENDAR QUARTER;

5.2 LICENSEE shall maintain and cause its AFFILIATES and sublicensees to maintain, complete and accurate books and records in accordance with generally accepted accounting principles consistently applied that enable the royalties and other payments due hereunder to be verified. The records for each CALENDAR QUARTER shall be maintained for seven (7) years after the submission of each report under Section 5.1 hereof. Upon reasonable prior notice to LICENSEE, LICENSOR and its accountants shall have access to all books and records relating to the reports due under Section 5.1 and the payments due under Article 4, as well as the diligence requirements and reports under Article 6 sufficient to conduct a review and audit thereof. Such access shall be available not more than once each CALENDAR YEAR, during normal business hours, and for each of three (3) years after the expiration or termination of this AGREEMENT. If LICENSOR determines that LICENSEE has underpaid undisputed royalties or other undisputed payments due by five percent (5%) or more, LICENSEE will pay the costs and expenses of LICENSOR and its accountants in connection with their review and/or audit. LICENSEE will pay any undisputed overdue amounts as well as late interest charges within fourteen (14) days of notification to it of underpayment with supporting documentation.

5.3 Beginning six (6) months after the RESTATEMENT DATE, and semi-annually thereafter until the later of five years after the RESTATEMENT DATE or one year after this AGREEMENT has been terminated or expires, LICENSEE shall submit to LICENSOR a progress report covering LICENSEE'S activities related to the research, development and testing of all LICENSED PRODUCTS and the obtaining of applicable governmental approvals necessary for marketing. These progress reports shall be made for each LICENSED PRODUCT in each country of the TERRITORY. Beginning on the sixth anniversary of the RESTATEMENT DATE, such progress reports shall be submitted annually instead of semiannually, with the last report due one year after this AGREEMENT has been terminated or expires.

5.4 The progress reports submitted under Section 5.3 shall include sufficient information to enable LICENSOR to determine LICENSEE'S progress in fulfilling its obligations under Article 6, and shall follow the format of the document attached as Appendix C.

5.5 LICENSOR agrees to receive and maintain all information provided by LICENSEE under this Article 5, including but not limited to royalty reports, in confidence to the same extent described in Section 3.6, except such information which falls under any exception described in Sections 7.1.1 through 7.1.3.

ARTICLE 6- DILIGENCE

6.1 LICENSEE shall use commercially reasonable efforts, and require its sublicensees and further sublicensees to use commercially reasonable efforts, to develop and make commercially available LICENSED PRODUCT(S) for commercial sales and distribution in a timely manner and create and fulfill market demand for such LICENSED PRODUCTS in at least the United States, Europe and Japan.

6.2 Prior to signing this Agreement, LICENSEE has provided to LICENSOR the Commercial Development Plan attached hereto as Appendix B, under which LICENSEE intends to bring LICENSED PRODUCTS to market. LICENSOR shall have full opportunity to review, comment on, and approve the final, mutually agreed Plan prior to execution of this Agreement. PERFORMANCE BENCHMARKS means those diligence goals and dates defined in the Commercial Development Plan.

6.3 As provided in Article 5, LICENSEE shall provide written reports on its product development progress or efforts to commercialize under the Commercial Development Plan. If reported progress differs from that projected in the Commercial Development Plan, LICENSEE shall explain the reasons for such differences. In the event that a substantial change in laws or regulations or feedback following interactions with the FDA affects the approval process in a material way or the Commercial Development Plan for any LICENSE PRODUCT(s) hereunder, and prevents LICENSEE from meeting any of the PERFORMANCE BENCHMARKS or milestone dates set forth in the Commercial Development Plan, LICENSOR and LICENSEE agree to negotiate in good faith a reasonable change in the dates so affected.

6.4 Subject to Section 6.3, LICENSEE may amend the PERFORMANCE BENCHMARKS at any time upon written consent by LICENSOR. LICENSOR shall not unreasonably withhold approval of any request of LICENSEE to extend the time periods associated with the PERFORMANCE BENCHMARKS if such request is supported by a reasonable showing by LICENSEE of diligence in its performance under the Commercial Development Plan.

6.5 On or about the anniversary date of this Agreement, LICENSOR shall have the right to call for a half-day, detailed review meeting during which LICENSEE and representatives of sublicensees, if any, and LICENSOR shall discuss the progress reports submitted by LICENSEE pursuant to Article 5 hereof. These meetings shall be held at LICENSEE's facility under appropriate confidentiality and LICENSEE will encourage its scientists and staff to provide full and detailed information to enable LICENSOR to evaluate the progress reports submitted by LICENSEE and to evaluate proposed amendments to the Commercial Development Plan as described in this Section 6.

6.6 LICENSOR agrees to receive and maintain all information provided by LICENSEE under this Article 6, including but not limited to the Commercial Development Plan and modifications thereto, in confidence, to the same extent described in Section 3.6, except such information which falls under any exception described in Sections 7.1.1 through 7.1.3.

ARTICLE 7 – CONFIDENTIALITY

7.1 Each PARTY shall maintain in confidence, and hereby agrees not to disclose to any third party, and use only to perform its obligations under this AGREEMENT all CONFIDENTIAL INFORMATION received pursuant to this AGREEMENT. Each PARTY agrees to ensure that its employees and sublicensees have access to CONFIDENTIAL INFORMATION only on a need-to-know basis and shall treat the CONFIDENTIAL INFORMATION with the same level of confidentiality with which each PARTY treats its own CONFIDENTIAL INFORMATION, but no less than reasonable care. The foregoing obligations shall not apply to:

7.1.1 information that is known to LICENSEE or independently developed by LICENSEE prior to the time of disclosure, in each case, to the extent evidenced by written records promptly disclosed to LICENSOR after receipt of the CONFIDENTIAL INFORMATION; or

7.1.2 information disclosed to LICENSEE by a third party that has a right to make such disclosure without restriction; or

7.1.3 information that is or becomes patented, published or otherwise part of the public domain as a result of acts by LICENSOR or a third person obtaining such information as a matter of right, including the right to publish; or

7.1.4 information that is required to be disclosed by order of governmental authority or a court of competent jurisdiction; provided that LICENSEE shall use its best efforts to obtain confidential treatment of such information by the agency or court; or

7.1.5 TECHNICAL INFORMATION that is necessary or helpful to be disclosed in order for LICENSED PRODUCT(S) to be developed and commercialized as intended herein by the parties, including any disclosure required or helpful to obtain or expedite regulatory approval, provided LICENSEE uses reasonable efforts to disclose such information under obligations of confidentiality and limited use comparable to those contained in this Section 7.1.

7.2 The confidentiality and use obligations set forth in Section 7.1 herein shall apply during the term of this AGREEMENT and for three (3) years after termination or expiration of this AGREEMENT.

ARTICLE 8 - TERM AND TERMINATION

8.1 Unless otherwise terminated by operation of law or by acts of the parties in accordance with the provisions of this AGREEMENT, this AGREEMENT shall commence on the RESTATEMENT DATE and shall remain in effect in each country until the expiration of the last-to-expire PATENT RIGHTS licensed under this AGREEMENT or seven and one-half (7.5) years from the date of first commercial sale of a LICENSED PRODUCT in such country, whichever is later.

8.2 LICENSEE may, at its option, terminate this AGREEMENT at any time by doing all of the following:

8.2.1 by ceasing to develop, register, make, have made, use and sell all LICENSED PRODUCT(S);

8.2.2 by terminating all sublicenses, and causing all sublicensees to cease developing, registering, making, having made, using and selling all LICENSED PRODUCT(S);

8.2.3 by giving one hundred eighty (180) days written notice to LICENSOR of such cessation and of LICENSEE'S intent to terminate;

8.2.4 by tendering payment of all accrued royalties and amounts due under this AGREEMENT as of the last day of the 180 day period referred to in Section 8.2.3.

8.3 LICENSOR may terminate this AGREEMENT if any of the following occur:

8.3.1 LICENSEE becomes more than sixty (60) days in arrears of any payments due to LICENSOR pursuant to this AGREEMENT, and LICENSEE does not provide full payment within thirty (30) business days after written demand therefor by LICENSOR; or

8.3.2 LICENSEE becomes subject to a BANKRUPTCY EVENT; or

8.3.3 LICENSEE otherwise breaches this AGREEMENT and does not cure such breach within sixty (60) days written notice thereof. Breaches shall include, without limitation, failure to make any royalty or progress report when due under this AGREEMENT and failure to exercise required diligence efforts under Article 6, including failure to successfully complete any diligence requirement described in Article 6; provided, however, than any such termination pursuant to Article 6 shall be limited to only those fields for which LICENSEE has failed to complete such diligence requirements and no termination shall be possible in the event there has been a change in law or regulation, or in the event an action, omission or other feedback, recommendation, decision or guidance from the FDA is determined to materially affect the ability of LICENSEE to meet its obligations under Article 6.

8.3.4 Nine (9) years have elapsed from the RESTATEMENT DATE, LICENSEE, an AFFILIATE or a sublicensee has not commenced commercial sales of at least one LICENSED PRODUCT, and LICENSOR has given LICENSEE ninety (90) days' notice of intent to terminate.

8.4 If LICENSEE becomes subject to a BANKRUPTCY EVENT, all duties of LICENSOR and all rights (but not duties) of LICENSEE under this AGREEMENT shall immediately terminate without the necessity of any action being taken either by LICENSOR or by LICENSEE

8.5 LICENSEE'S accrued obligations under all provisions of this Agreement shall survive early termination or expiration of this AGREEMENT. In addition, the provisions of Sections 3.4, 3.5, 8.5, 8.6, 8.7, 9.7, 10.6 and Articles 5, 7, 11, 12 and 13 shall survive such early termination or expiration.

8.6 Any termination or expiration of this AGREEMENT shall not relieve LICENSEE of any obligation or liability accrued hereunder prior thereto or rescind anything done by LICENSEE or any payments made to LICENSOR prior thereto, and such termination or expiration shall not affect in any manner any rights of LICENSOR arising under this AGREEMENT prior to such termination or expiration.

8.7 Upon early termination or expiration of this AGREEMENT, LICENSEE shall within sixty (60) days return to LICENSOR all TECHNICAL INFORMATION and CONFIDENTIAL INFORMATION. The parties shall negotiate in good faith regarding LICENSOR'S right to receive and use data generated by or for LICENSEE that may facilitate the development or commercialization of the technology licensed hereunder.

ARTICLE 9 - PATENT MAINTENANCE AND REIMBURSEMENT

9.1 LICENSEE shall, at its expense, manage, direct and shall have sole responsibility and discretion in decisions respecting the preparation, filing, prosecution, maintenance, defense, and abandonment of the PATENT RIGHTS licensed hereunder, using counsel of its choice (chosen with the consent of LICENSOR, which consent will not be unreasonably withheld). LICENSOR consents to the use of McCarter & English, MH2 Technology Law Group, and any other counsel the parties may mutually agree upon in the future. LICENSEE shall instruct counsel to copy LICENSOR on all communications related to prosecution of the PATENT RIGHTS. LICENSEE'S counsel shall take instructions only from LICENSEE. LICENSEE shall keep LICENSOR informed and apprised of actions and decisions relating to the PATENT RIGHTS, including but not limited to providing copies of patent filings, office actions and communications from and to any patent offices and providing at least 60 days written notice to LICENSOR prior to (i) abandoning any of the PATENT RIGHTS or (ii) failing to defend any of the PATENT RIGHTS.

9.1.1 LICENSEE shall be free to abandon PATENT RIGHTS at its discretion provided that it accords LICENSOR adequate notice of any such decision as specified in Section 9.1. In the event LICENSOR wishes to take over management of any PATENT RIGHTS which LICENSEE chooses to abandon, pursuant to the 60 day notice provided in Section 9.1, LICENSOR may do so upon written notice to LICENSEE.

9.1.2. LICENSEE shall be free to file or not file applications related to the PATENT RIGHTS in any country at its discretion. Should LICENSEE elect not to file a patent application in a country or countries, LICENSOR may file such application(s) using counsel of its choice upon written notice to LICENSEE.

9.1.3. After LICENSOR provides notice to LICENSEE pursuant to Section 9.1.1 or 9.1.2, LICENSOR shall be solely responsible, at its expense, for all aspects of management of such patent or patent application. LICENSEE shall remain responsible providing the information required under Section 9.1, and for paying for all costs incurred prior to the date that LICENSOR has taken responsibility. Thereafter, LICENSEE shall have not further rights in such PATENT RIGHTS, and LICENSOR shall have full discretion in how it wishes to manage them, including but not limited to licensing them to third parties.

9.2 Each party shall cooperate reasonably with the other's activities under Section 9.1, including but not limited to applying for an extension of the term of any patent included within PATENT RIGHTS if appropriate under the Drug Price Competition and Patent Term Restoration Act of 1984 as amended. Each party agrees to execute all documents and to take any additional action as the other may reasonably request in connection with activities under Section 9.1.

9.3 All unreimbursed past, present and future costs associated with preparing, filing, prosecuting, defending, and maintaining and management of the licensed PATENT RIGHTS shall be borne and promptly paid by LICENSEE; provided, however, any costs incurred by LICENSEE in recording that certain assignment of PATENT RIGHTS by BDSI to LICENSOR before the USPTO or any foreign patent office shall be credited against any payment owed to LICENSOR by LICENSEE under this Agreement.

9.4 After the RESTATEMENT DATE, upon periodic request by LICENSEE, LICENSOR shall advise LICENSEE of discoveries or inventions made by, under the direction or supervision of Dr. Mannino and owned by LICENSOR that have been formally disclosed to LICENSOR's technology transfer office and which LICENSOR considers may be of interest to LICENSEE and which are available for licensing to LICENSEE. If not covered by the PATENT RIGHTS, and should LICENSEE wish to license the intellectual property relating to such discoveries or inventions, the PARTIES will enter into good faith negotiations for the possible licensing of them to LICENSEE.

9.6 LICENSEE, its AFFILIATES and its sublicensees and their further sublicensees shall comply with all United States and foreign laws with respect to patent marking of LICENSED PRODUCT(S).

9.7 Upon expiration or early termination of this AGREEMENT, or the removal of any PATENT RIGHTS or claims thereof from this AGREEMENT, LICENSOR shall become responsible for such PATENT RIGHTS and/or claims, except for non-cancellable commitments made by and liabilities incurred by LICENSEE during the term of this AGREEMENT.

ARTICLE 10 - INFRINGEMENT AND LITIGATION

10.1 LICENSOR and LICENSEE are responsible for notifying each other promptly of any infringement of PATENT RIGHTS that may come to their attention. The parties shall consult with one another in a timely manner concerning any appropriate response thereto.

10.2 LICENSEE shall have the right, but not the obligation to prosecute such infringement at its own expense. At LICENSEE'S request and expense, LICENSOR will reasonably cooperate by joining as a party plaintiff if required to do so by law to maintain such action or proceeding and by executing and making available such documents as LICENSEE may reasonably request. LICENSEE shall have the right to settle any claim or suit for infringement of the PATENT RIGHTS with prior approval of LICENSOR, including by granting the infringing party a sublicense to the PATENT RIGHTS pursuant to Article 3 of this AGREEMENT. LICENSEE shall not settle or compromise any such suit in a manner that imposes any obligations or restrictions on LICENSOR without LICENSOR'S written permission, such permission not to be unreasonably withheld. Any excess financial recovery, after all litigation costs and expenses have been paid, shall be apportioned between LICENSEE and LICENSOR with **[*]** to LICENSEE and **[*]** to LICENSOR.

10.3 LICENSEE'S rights in Section 10.2 shall be subject to the continuing right of LICENSOR to intervene at LICENSOR's own expense and join LICENSEE in any claim or suit for infringement of the PATENT RIGHTS. Any consideration received by LICENSEE in settlement of any claim or suit shall be shared between LICENSOR and LICENSEE in proportion with their share of the litigation expenses in such infringement action, but LICENSOR shall in no event receive less than the percentage share it is entitled to under Section 10.2.

10.4 If LICENSEE fails to prosecute such infringement, LICENSOR shall have the right, but not the obligation, to prosecute such infringement at its own expense. In such event, financial recoveries will be entirely retained by LICENSOR.

10.5 In any action to enforce any of the PATENT RIGHTS, either party, at the request and expense of the other party, shall cooperate to the fullest extent reasonably possible. This provision shall not be construed to require either party to undertake any activities, including legal discovery, at the request of any third party except as may be required by lawful process of a court of competent jurisdiction.

10.6 This Article 10 shall survive expiration or termination of this AGREEMENT to the extent any litigation has been commenced hereunder prior to expiration or termination.

ARTICLE 11 - DISCLAIMER OF WARRANTY, INDEMNIFICATION AND INSURANCE

11.1 THE PATENT RIGHTS AND TECHNICAL INFORMATION ARE PROVIDED ON AN "AS IS" BASIS, AND NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, ARE MADE WITH RESPECT THERETO. BY WAY OF EXAMPLE BUT NOT OF LIMITATION, NO REPRESENTATIONS OR WARRANTIES ARE MADE (i) OF COMMERCIAL UTILITY; (ii) OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE; OR (iii) THAT THE USE OF THE PATENT RIGHTS, TECHNICAL INFORMATION, OR THAT MAKING, USING OR SELLING LICENSED PRODUCT(S) WILL NOT INFRINGE ANY PATENT, COPYRIGHT OR TRADEMARK OR OTHER PROPRIETARY OR PROPERTY RIGHTS OF OTHERS. LICENSOR AND BDSI SHALL NOT BE LIABLE TO LICENSEE, ITS AFFILIATES, OR THEIR RESPECTIVE SUCCESSORS OR ASSIGNS OR ANY THIRD PARTY WITH RESPECT TO: ANY CLAIM ARISING FROM THE USE OF THE PATENT RIGHTS OR TECHNICAL INFORMATION, OR FROM THE MANUFACTURE, USE OR SALE OF LICENSED PRODUCT(S); OR ANY CLAIM FOR LOSS OF PROFITS, LOSS OR INTERRUPTION OF BUSINESS, OR FOR, DIRECT, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES OF ANY KIND.

11.2 To the maximum extent permitted by applicable law, LICENSEE shall defend, indemnify and hold harmless LICENSOR, BDSI, and their respective trustees, officers, agents and employees (individually, an "Indemnified Party", and collectively, the "Indemnified Parties"), from and against any and all liability, loss, damage, action, claim or expense suffered or incurred by the Indemnified Parties (including attorney's fees) (individually, a "Liability", and collectively, the "Liabilities") that results from or arises out of: (i) the development, use, manufacture, promotion, sale or other disposition, of any TECHNICAL INFORMATION, PATENT RIGHTS or LICENSED PRODUCT(S) by LICENSEE, its AFFILIATES or their respective assignees, sublicensees and their further sublicensees, vendors or other third parties; (ii) breach by LICENSEE or its AFFILIATE(S) of any covenant or agreement contained in this AGREEMENT; and (iii) the enforcement by an Indemnified Party of its rights under this Section. Without limiting the foregoing, LICENSEE will defend, indemnify and hold harmless the Indemnified Parties from and against any Liabilities resulting from:

11.2.1 any product liability or other claim of any kind related to the use by a third party of a LICENSED PRODUCT(S) that was developed, manufactured, used, sold or otherwise disposed of by LICENSEE, its AFFILIATES or their assignees, sublicensees and their further sublicensees, vendors or other third parties; and/or

11.2.2 a claim by a third party that the TECHNICAL INFORMATION or PATENT RIGHTS or the design, composition, manufacture, use, sale or other disposition of any LICENSED PRODUCT(S) infringes or violates any patent, copyright, trademark or other intellectual property rights of such third party other than claims that result solely from the actions of LICENSOR or its agents.

11.3 The Indemnified Party shall notify LICENSEE of any claim or action giving rise to Liabilities subject to the provisions of the foregoing Section. LICENSEE shall have the obligation to defend any such claim or action, at its cost and expense. LICENSEE shall not settle or compromise any such claim or action in a manner that imposes any restrictions or obligations on LICENSOR without LICENSOR'S prior written consent. If LICENSEE fails or declines to assume the defense of any such claim or action within thirty (30) days after notice thereof, LICENSOR may assume the defense of such claim or action for the account of and risk of LICENSEE, and any Liabilities related thereto shall be conclusively deemed a liability of LICENSEE. LICENSEE shall pay promptly to the Indemnified Party any Liabilities to which the foregoing indemnity relates, as incurred. The indemnification rights of LICENSOR or other Indemnified Party contained herein are in addition to all other rights which such Indemnified Party may have at law or in equity or otherwise.

11.4 LICENSEE shall procure and maintain a policy or policies of comprehensive general liability insurance, including broad form and contractual liability, in a minimum amount of $1,000,000 combined single limit per occurrence and in the aggregate as respects personal injury, bodily injury and property damage arising out of LICENSEE'S or its AFFILIATE(S) performance of this AGREEMENT. LICENSEE insurance shall be primary coverage, and LICENSOR insurance or self-insurance shall be excess coverage and non-contributory.

11.5 The policy or policies of insurance specified herein shall be issued by an insurance carrier with an A.M. Best rating of "A" or better and shall name LICENSOR and BDSI as additional insureds with respect to LICENSEE'S performance of this AGREEMENT. LICENSEE shall provide LICENSOR with certificates evidencing the insurance coverage required herein and all subsequent renewals thereof. Such certificates shall provide that LICENSEE'S insurance carrier(s) notify LICENSOR in writing at least thirty (30) days prior to cancellation or material change in coverage.

11.6 LICENSOR shall periodically review the adequacy of the minimum limits of liability specified herein. Following such review and based upon LICENSOR's good faith determination that such minimum limits of liability specified herein are no longer adequate, LICENSOR reserves the right to require LICENSEE to adjust such coverage limits accordingly; provided, however, LICENSEE's inability to comply with such request shall not be considered a breach of this AGREEMENT nor form the basis of termination under Article 8. The specified minimum insurance amounts shall not constitute a limitation on LICENSEE'S obligation to indemnify LICENSOR or other Indemnified Parties under this AGREEMENT.

ARTICLE 12 - USE OF LICENSOR'S NAME; INDEPENDENT CONTRACTOR

12.1 LICENSEE and its employees and agents shall not use and LICENSEE shall not permit its AFFILIATES or sublicensees to use LICENSOR'S name, any adaptation thereof, any LICENSOR logotype, trademark, service mark or slogan or the name mark or logotype of any LICENSOR representative or organization in marketing or advertising materials, or in a manner that implies endorsement, without the prior written consent of LICENSOR in each instance, which consent will not be unreasonably withheld.

12.2 Nothing herein shall be deemed to establish a relationship of principal and agent between LICENSOR and LICENSEE, nor any of their agents or employees for any purpose whatsoever. This AGREEMENT shall not be construed as constituting LICENSOR and LICENSEE as partners, or as creating any other form of legal association or arrangement that would impose liability upon one party for the act or failure to act of the other party.

ARTICLE 13 - MISCELLANEOUS PROVISIONS

13.1 LICENSEE shall comply with all prevailing laws, rules and regulations pertaining to the development, testing, manufacture, marketing, sale, use, import or export of LICENSED PRODUCT(S). Without limiting the foregoing, it is understood that this AGREEMENT may be subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities, articles and information, including the Arms Export Control Act as amended in the Export Administration Act of 1979, and that the parties' obligations hereunder are contingent upon compliance with applicable United States export laws and regulations. The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by LICENSEE that LICENSEE shall not export data or commodities to certain foreign countries without prior approval of such agency. LICENSOR neither represents that a license is not required nor that, if required, it will issue.

13.2 This AGREEMENT will be binding on the parties hereto and upon their respective successors and assigns. LICENSEE may at any time, upon written notice to LICENSOR, assign this AGREEMENT to a purchaser of all of its business, provided such assignment does not adversely affect LICENSOR'S rights hereunder. Except as provided above, LICENSEE will not assign this AGREEMENT, or delegate any right or obligation hereunder without the prior written consent of LICENSOR, which consent may not be unreasonably withheld. LICENSOR may assign this AGREEMENT at any time to Rutgers, the State University of New Jersey. Any attempted assignment or delegation in violation of this Section 13.2 will be void.

13.3 Notices, payments, statements, reports and other communications under this AGREEMENT shall be in writing and shall be deemed to have been received (i) when personally delivered, or (ii) five (5) days after mailing if mailed by first-class certified mail, postage paid and deposited in the United States mail, or (iii) as of the date dispatched if sent by public overnight courier (e.g., Federal Express), or (iv) or as otherwise agreed upon in writing by the parties and addressed as follows:

If for LICENSOR:

Director, Biomedical and Life Sciences Licensing
Office of Technology Commercialization
Rutgers, The State University of New Jersey
ASB Annex III, 3 Rutgers Plaza
New Brunswick, New Jersey 08901-8559

If for LICENSEE:

Dr. J Carl Craft, M.D.
CEO
Aquarius Biotechnologies, Inc.
2037 W. Carroll Avenue
Chicago, IL 60612

Either party may change its official address upon written notice to the other party.

13.4 This AGREEMENT shall be construed and governed in accordance with the laws of the State of New Jersey, without giving effect to conflict of law provisions, but the scope and validity of any patent or patent application shall be governed by the applicable laws of the country of such patent or patent application.

13.5 This AGREEMENT embodies the entire understanding of the parties and shall supersede all previous and contemporaneous communications, representations or understandings, either oral or written, between the parties relating to the subject matter hereof. Any modification of this AGREEMENT shall be in writing and signed by an authorized representative of each party.

13.6 In the event that a party to this AGREEMENT perceives the existence of a dispute with the other party concerning any right or duty provided for herein, the parties shall, as soon as practicable, confer in an attempt to resolve the dispute. If the parties are unable to resolve such dispute amicably within ninety (90) days of initial notice of dispute by one party to the other party, then the parties hereby submit to the exclusive jurisdiction of and venue in the courts located in the State of New Jersey with respect to any and all disputes relating to this AGREEMENT.

13.7 A waiver by either party of a breach or violation of any provision of this AGREEMENT will not constitute or be construed as a waiver of any subsequent breach or violation of that provision or as a waiver of any breach or violation of any other provision of this AGREEMENT or a subsequent breach of the same provision.

13.8 In case any of the provisions contained in this AGREEMENT shall be held to be invalid, illegal or unenforceable in any respect in any jurisdiction, (i) such invalidity, illegality or unenforceability shall not affect any other provisions hereof, (ii) the particular provision, to the extent permitted by law, shall be reasonably construed and equitably reformed to be valid and enforceable and if the provision at issue is a commercial term, it shall be equitably reformed so as to maintain the overall economic benefits of the AGREEMENT as originally agreed upon by the parties, and (iii) this AGREEMENT shall be construed as if such invalid or illegal or unenforceable provisions had never been contained herein.

13.9 The headings and captions used in this AGREEMENT are for convenience of reference only and shall not affect its construction or interpretation.

13.10 Nothing in this AGREEMENT, express or implied, is intended to confer on any person, other than the parties hereto or their permitted assigns, any benefits, rights or remedies.

13.11 Neither LICENSEE nor its AFFILIATES shall originate any publicity, news release or other public announcement, written or oral, relating to this AGREEMENT or the existence of an arrangement between the parties, except as required by law or any applicable securities exchange rules (including, without limitation, provisions regarding the disclosure requirements required by the U.S. Securities and Exchange Commission for publicly quoted companies provided that such party required to file or disclose shall seek appropriate confidential treatment and shall seek to minimize such disclosure), without the prior written approval of the LICENSOR, which approval shall not be unreasonably withheld. Each party shall respond to a request for approval from the other party within thirty (30) days after receipt of the request.

13.12 This AGREEMENT may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

13.13 LICENSEE shall not enter into any agreements relating to this AGREEMENT with any of the INVENTORS or other LICENSOR employees or students in contravention of the legal rights or policies of LICENSOR or without the prior written consent of LICENSOR, which consent shall not be unreasonably withheld.

13.14 In the event of a failure of performance due under the terms of this AGREEMENT by either party, if the other party undertakes legal action against the non-performing party on account thereof, then the party undertaking legal action shall be entitled to reasonable attorneys' fees in addition to costs and disbursements if it prevails in such legal action.

[*End of Agreement – Signature Pages To Follow*]

IN WITNESS WHEREOF the parties, intending to be legally bound, have caused this AGREEMENT to be executed by their duly authorized representatives on the date first set forth above.

FOR LICENSOR:	/s/ David Kimball, Ph.D.
By:	S. David Kimball, Ph.D.
Title:	Associate Vice President, Research Commercialization Office of Research and Economic Development
DATE:	January 29, 2015

FOR LICENSEE:	/s/ J Carl Craft
By:	J Carl Craft
Title:	Chief Executive Officer
Date:	January 29, 2015

APPENDIX A (i)

Table I. Solely Owned by Rutgers

Title	Country	Appln. No.	Patent No.
[*]	[*]	[*]	[*]
[*]	[*]	[*]	
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	
[*]	[*]	[*]	
[*]	[*]	[*]	[*]
[*]	[*]	[*]	
[*]	[*]	[*]	[*]

Table I. Solely Owned by Rutgers (cont'd)

Title	Country	Appln. No.	Patent No.
[*]	[*]	[*]	
[*]	[*]	[*]	
[*]	[*]	[*]	
[*]	[*]	[*]	

Table II. Co-Owned by Rutgers

Title	Country	Appln. No.	Patent No.
[*]	[*]	[*]	
[*]	[*]	[*]	
[*]	[*]	[*]	

APPENDIX A (ii)

[*]

APPENDIX B – Commercial Development Plan

As the cochleate technology is a drug delivery platform with broad potential applications, there are many potential development routes that would lead to a commercial product utilizing cochleates. These development routes include pharmaceutical applications and non-pharmaceutical applications, such as food and cosmetics.

Diligence terms are listed below for both pharmaceutical and non-pharmaceutical products. The PHARMACEUTICAL PRODUCT field shall mean the treatment of any disease or condition. The NON-PHARMACEUTICAL PRODUCT field shall mean all fields except the treatment of any disease or condition.

PHARMACEUTICAL PRODUCT Diligence Terms

General

LICENSEE, an AFFILIATE or a sublicensee will ensure on-going development of one or more LICENSED PRODUCTS by continued annual expenditure for direct costs of no less than **[*]** annually during the first year after the Restatement Date and **[*]** annually thereafter.

For Pharmaceutical Products other than encochleated Amphotericin B or Amikacin*[*]*:

LICENSEE, an AFFILIATE or a sublicensee will **[*]**.
LICENSEE, an AFFILIATE or a sublicensee will **[*]**.
LICENSEE, an AFFILIATE or a sublicensee will **[*]**.
LICENSEE, an AFFILIATE or a sublicensee will **[*]**.
LICENSEE, an AFFILIATE or a sublicensee will **[*]**.

Development Plan Disclaimer

LICENSOR and LICENSEE acknowledge and agree that during the course of normal pharmaceutical development certain key findings: (i) may provide opportunities for accelerated development, either under fast track FDA review or under alternative regulatory pathways such 505(b)(2), and LICENSEE commits to exploit such opportunities for rapid development as is commercially reasonable; (ii) may reveal issues related to safety/tolerability or lack of efficacy, or may result in FDA advise/action adversely affecting the development plan for a certain pharmaceutical product; or (iii) significant development progress or regulatory approval of competing products may affect clinical utility or commercial competitiveness, such that items (ii) and (iii) may require assessment of any viable development pathways given such findings and potential adjustment of the development or abandonment of the program if further development is no longer commercially reasonable.

For Pharmaceutical Products comprising encochlaeted Amphotericin B:

- Amphotericin B is a fungicidal (as opposed to fungistatic) broad spectrum antifungal. As of the Restatement Date, the program for encochleated Amphotericin B has completed a one dose escalating (200-800mg) single dose oral administration PK study, with favorable tolerability. **[*]**.

- In collaboration with NIH-NIADD, LICENSEE is developing a protocol for an open label Phase 2a efficacy study of patients with refractory mucocutaneous Candidiasis, also incorporating single and multiple dose PK in such patients. **[*]**.

[*].

For Pharmaceutical Products comprising encochleated Amikacin:

- Amikacin is an aminoglycoside antibiotic with broad spectrum activity against many gram-negative bacteria. **[*]**.

- As of the RESTATEMENT DATE, the encochleated Amikacin has undergone **[*]**

- **[*]**

- **[*]**

NON-PHARMACEUTICAL PRODUCT diligence terms

LICENSEE, an AFFILIATE or a sublicensee will commence a **[*]** of at least one LICENSED PRODUCT in the NON-PHARMACEUTICAL field within **[*]** of the RESTATEMENT DATE in the **[*]**.

APPENDIX C – PROGRESS REPORT TEMPLATE

Licensee:
Program:
Reporting Period:

- Upon the first anniversary of the Restatement Date of the License, please modify/complete the attached schematic (Appendix B) or submit a similar schematic that provides an overview of the proposed development program, including key milestones (regulatory and commercial). Submit a revised version of the plan when adjustments to the timeline occur;

- For the reporting period, provide a summary of work completed, including key scientific results and a brief interpretation of pre-clinical/clinical findings;

- For the upcoming reporting period, provide an overview of work in progress or to be initiated related to drug candidate development and testing;

- Report on the estimated timings or status (e.g., meeting requested, identify the date when a meeting occurred, preparation of filing in process) of the following regulatory milestones:

    - Pre-IND discussions with FDA
    - IND filing
    - End of Ph2 meeting with FDA
    - NDA filing
    - NDA approval

- Upon initiation of Ph2 summarize the expected period of exclusivity/time on the market for the launched LICENSED PRODUCT;

- Upon initiation of Ph2 please summarize: i) existing standard of care for the anticipated lead indication; and ii) how the LICENSED PRODUCT will meet existing unmet needs/differentiate from launched products;

- Upon completion of Ph2 please summarize the selling and promotion strategy for the launched LICENSED PRODUCT (e.g., use of existing sales force; establishment of sales force; or partner to access established sales force);
- Describe activities relating to obtaining sublicenses and activities of sublicensees;
- Report on IP milestones relating to the licensed IP, including costs associated with filings, prosecution or maintenance;
- Provide a summary of resources (dollar value) spent in the reporting period for research, development and marketing of LICENSED PRODUCTS;
- Provide uncertified and certified (audited/unaudited) financial statement as of the end of the previous calendar quarter.

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 S-1 (No. 333-193455) and Registration Statement Form S-8 (File No. 333-198488) of our report dated March 30, 2015, on our audits of the consolidated financial statements as of December 31, 2014 and 2013, 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, 2015

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, 2014 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 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)) 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) [Omitted.];

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

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

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

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

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

Date: March 30, 2015

/s/ Roelof Rongen
Roelof Rongen
President and 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, 2014 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 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)) 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) [Omitted.];

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

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

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

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

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

Date: March 30, 2015

/s/ Gary Gaglione
Gary Gaglione
Acting Chief Financial Officer
(Principal Accounting and Financial Officer)

Exhibit 32.1

CERTIFICATION OF THE PRINCIPAL EXECUTIVE 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, 2014 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Roelof Rongen, President and 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, 2015

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

Date: March 30, 2015

/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.