PALATIN TECHNOLOGIES INC
Form 10-K
September 10, 2012

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

FORM 10 - K

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

For the fiscal year ended June 30, 2012

or

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

For the transition period from _____ to _____

Commission file number: 001-15543

PALATIN TECHNOLOGIES, INC.
(Exact name of registrant as specified in its charter)

| Delaware | 95-4078884 |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| 4B Cedar Brook Drive<br>Cranbury, New Jersey<br>(Address of principal executive offices) | 08512<br>(Zip Code) |

(609) 495-2200
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

| Title of Each Class | Name of Each Exchange on Which Registered |
|---|---|
| Common Stock, par value $.01 per share | NYSE MKT |

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 o No x

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No o

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the 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. o

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 o | Accelerated filer o |
| Non-accelerated filer o (Do not check if a smaller reporting company) | Smaller reporting company x |

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates, computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter (December 31, 2011): $13,870,532.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date (September 7, 2012): 38,947,912.

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PART I

Item 1. Business.

Forward-looking statements

Statements in this Annual Report on Form 10-K (this Annual Report), as well as oral statements that may be made by us or by our officers, directors, or employees acting on our behalf, that are not historical facts constitute "forward-looking statements," which are made pursuant to the safe harbor provisions of Section 21E of the Securities Exchange Act of 1934 (the Exchange Act). The forward-looking statements in this Annual Report do not constitute guarantees of future performance. Investors are cautioned that statements which are not strictly historical statements contained in this Annual Report, including, without limitation, current or future financial performance, management's plans and objectives for future operations, ability to raise capital or repay debt, if required, clinical trials and results, uncertainties associated with product research and development, product plans and performance, management's assessment of market factors, as well as statements regarding our strategy and plans and those of our strategic partners, constitute forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to be materially different from our historical results or from any results expressed or implied by such forward-looking statements. Our future operating results are subject to risks and uncertainties and are dependent upon many factors, including, without limitation, the risks identified under the caption "Risk Factors" and elsewhere in this Annual Report, as well as in our other Securities and Exchange Commission (SEC) filings.

In this Annual Report, references to "we," "our," "us" or "Palatin" means Palatin Technologies, Inc. and its subsidiary.

Overview

We are a biopharmaceutical company developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential. Our programs are based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. Our primary product in clinical development is bremelanotide for the treatment of female sexual dysfunction (FSD). In addition, we have drug candidates or development programs for obesity, erectile dysfunction, pulmonary diseases, cardiovascular diseases and inflammatory diseases.

The following drug development programs are actively under development:

- Bremelanotide, a peptide melanocortin receptor agonist, for treatment of FSD. This drug candidate is in Phase 2B clinical trials.

- Melanocortin receptor-based compounds for treatment of obesity, under development by AstraZeneca AB (AstraZeneca) pursuant to our research collaboration and license agreement.

- PL-3994, a peptide mimetic natriuretic peptide receptor A (NPR-A) agonist, for treatment of cardiovascular and pulmonary indications.

The following chart shows the status of our drug development programs.

We have initiated preclinical studies with new peptide drug candidates for a number of indications, primarily inflammatory disease related, and are continuing preclinical development with a next generation peptide for FSD and

erectile dysfunction.

On July 3, 2012, we closed on a private placement of 3,873,000 shares of our common stock, Series A 2012 warrants to purchase up to 31,988,151 shares of our common stock, and Series B 2012 warrants to purchase up to 35,488,380 shares of our common stock. Aggregate gross proceeds to us were $35,000,000, with net proceeds, after deducting estimated offering expenses, of approximately $34,500,000. The Series B 2012 warrants are exercisable only if our stockholders increase the number of our authorized shares of common stock, and we have certain contractual obligations, including an obligation to pay interest on Series B 2012 warrants and to redeem Series B 2012 warrants, in the event that the number of our authorized shares of common stock is not increased by specified dates. See “Risk Factors” below.

Key elements of our business strategy include: using our technology and expertise to develop and commercialize innovative therapeutic products; entering into alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of product candidates that we are developing; and, partially funding our product development programs with the cash flow generated from our license agreement with AstraZeneca and any other companies.

We incorporated in Delaware in 1986 and commenced operations in the biopharmaceutical area in 1996. Our corporate offices are located at 4B Cedar Brook Drive, Cranbury, New Jersey 08512 and our telephone number is (609) 495-2200. We maintain an Internet site at http://www.palatin.com, where among other things, we make available free of charge on and through this website our Forms 3, 4 and 5, annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) and Section 16 of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Our website and the information contained in it or connected to it are not incorporated into this Annual Report.

Melanocortin Receptor-Specific Programs

The melanocortin system is involved in a large and diverse number of physiologic functions, and therapeutic agents modulating this system may have the potential to treat a variety of conditions and diseases, including sexual dysfunction, obesity and related disorders, pigmentation disorders and inflammation-related diseases.

Bremelanotide for Female Sexual Dysfunction (FSD). We are developing subcutaneously administered bremelanotide for the treatment of FSD in premenopausal women. Bremelanotide, which is a melanocortin agonist (a compound which binds to a cell receptor and activates a response), is a synthetic peptide analog of the naturally occurring hormone alpha-MSH (melanocyte-stimulating hormone).

Ongoing Clinical Trials. The last patient has completed treatment in our ongoing Phase 2B clinical trial with bremelanotide for treatment of FSD. We anticipate database lock by the end of September and completing primary data analysis and announcing top-line results in the first-half of the fourth quarter of calendar 2012. This multicenter study is a placebo-controlled, randomized, parallel group, dose-finding trial testing three dose levels of subcutaneously administered bremelanotide in premenopausal women diagnosed with female sexual arousal disorder and/or hypoactive sexual desire disorder. The study enrolled premenopausal women across 66 sites within the United States and Canada, with patients randomized to one of three treatment arms and a placebo arm for 16 weeks of treatment. The objective of the Phase 2B trial is to measure safety and efficacy of subcutaneous doses intended for on-demand, home use. The primary efficacy endpoint is change from baseline to end of study in the number of satisfying sexual events. We can provide no assurance that the results of the Phase 2B trial will warrant continued development of bremelanotide as a treatment for FSD.

Medical Need - FSD. FSD is a multifactorial condition that has anatomical, physiological, medical, psychological and social components. FSD includes four disorders, hypoactive sexual desire disorder, female sexual arousal disorder, sexual pain disorder and orgasmic disorder. To establish a diagnosis of FSD, these syndromes must be associated with personal distress, as determined by the affected women. The 1992 National Health and Social Life Survey, a probability sample study of sexual behavior in a demographically representative cohort of United States adults ages 18 to 59, found that approximately 43% of women have symptoms associated with FSD, with up to about 15% having associated personal distress required to establish a diagnosis of FSD.

There are no drugs in the United States approved for FSD indications.

Subcutaneous Bremelanotide. Bremelanotide, which is believed to act through activation of melanocortin receptors in the central nervous system, is a first-in-class pharmaceutical agent in development as a treatment of FSD.

Bremelanotide is intended for “on-demand” use and is self-administered by the patient approximately one hour prior to anticipated sexual activity. We have evaluated delivery devices and believe that bremelanotide can be used with simple and patient-friendly disposable auto-injector device. If Phase 2 clinical trials for FSD are successful, we anticipate that Phase 3 clinical trials will be conducted with a delivery device intended for commercialization.

Clinical Trials with Intranasal Formulations. We extensively studied bremelanotide for sexual dysfunction using an intranasal formulation, administered as a single spray in one nostril. Increases in blood pressure were observed in some patients receiving nasally administered bremelanotide, and this observed increase was a significant factor leading us to discontinue work on nasally administered bremelanotide. We believe that the amount of increase in blood pressure, as well as the rate of nausea and emesis (vomiting), was due, at least partially, to high doses resulting from variability in drug uptake with nasal administration. Studies showed wide variation in plasma levels of bremelanotide in patients receiving nasally administered bremelanotide.

While we are no longer developing intranasal formulations of bremelanotide for commercialization, trials with intranasal formulations of bremelanotide did demonstrate potential utility of bremelanotide. Preliminary Phase 2A clinical trials of FSD patients showed statistically significant increases in the level of sexual desire and genital arousal in post-menopausal subjects receiving nasal bremelanotide and increases in the level of sexual desire and genital arousal in premenopausal subjects receiving nasal bremelanotide, although interpretation of results with premenopausal subjects was confounded by a significant placebo effect, which is often seen in such studies. Phase 2B double-blind, placebo-controlled, parallel doses clinical trials evaluating intranasal bremelanotide for erectile dysfunction (ED), conducted in 726 non-diabetic and 294 diabetic patients, showed that over 30% of ED patients were restored to a normal level of function. In trials conducted to date, almost 2,000 patients received at least one dose of bremelanotide, with about 1,500 receiving multiple doses.

Prior Clinical Trials with Subcutaneous Administration. We have completed several Phase 1 clinical studies in which blood pressure effects of subcutaneously administered bremelanotide were studied. These studies suggest that transient elevations of blood pressure are dependent on both the specific patient population and the dose administered. Our ongoing Phase 2B clinical trial, which assesses the magnitude and duration of blood pressure effect, addresses whether subcutaneous administration of selected doses of bremelanotide for treatment of FSD in premenopausal women will provide acceptable control of blood pressure effects.

Peptide Melanocortin Receptor Agonists for Treatment of Sexual Dysfunction. We have developed a series of next generation highly selective melanocortin receptor-specific peptides for treatment of sexual dysfunction. In developing these peptides, we examined effectiveness in animal models of sexual response and also determined cardiovascular effects, primarily looking at changes in blood pressure. Results of these studies suggest that certain of these peptides may have significant commercial potential for treatment of FSD and ED.

Obesity. In 2007, we entered into an exclusive research collaboration and license agreement with AstraZeneca to discover, develop and commercialize compounds that target melanocortin receptors for the treatment of obesity, diabetes and related metabolic syndrome. In June and December 2008 and in September 2009, the agreement was amended to include additional compounds and associated intellectual property that we developed and to modify royalty rates and milestone payments. Active work under the collaboration portion of the agreement concluded in January 2010.

AstraZeneca has discontinued development of AZD2820, a subcutaneously-administered peptide melanocortin receptor partial agonist that was being developed as a single-agent therapy for the treatment of obesity. The decision to discontinue development was made after a Phase 1 clinical trial of AZD2820 was halted following a serious adverse event. Based on an investigation, it could not be excluded that the serious adverse event was linked to AZD2820, but it was determined that it was unlikely that the serious adverse event was related to melanocortin agonists as a target for treatment of obesity. AstraZeneca has a number of collaboration compounds in various stages of preclinical testing, and remains committed to the research collaboration and continued advancement of melanocortin compounds for treatment of obesity.

Obesity is a multifactorial condition with numerous biochemical components relating to satiety (feeling full), energy utilization and homeostasis. A number of different metabolic and hormonal pathways are being evaluated by

companies around the world in efforts to develop better treatments for obesity. Scientific research has established that melanocortin receptors have a role in eating behavior and energy homeostasis, and that melanocortin receptor agonists can decrease food intake and induce weight loss.

Obesity is a significant healthcare issue, often associated with co-morbidities such as cardiovascular disease and diabetes. According to a 2011 fact sheet from the World Health Organization, more than 1.5 billion adults worldwide are overweight, with over 500 million categorized as obese. Overweight and obesity is the fifth leading risk for global deaths and the second leading cause of preventable death in the United States. About one-third of Americans are obese and another one-third are overweight. Medical costs in the United States associated with obesity were estimated at $147 billion for 2008.

We developed classes of small molecule and peptide compounds targeting melanocortin receptors which are effective in the treatment of obesity in animal models. Certain of these compounds have shown activity in animal models of both diet-induced and genetically derived obesity. These compounds appear to decrease food intake and body weight without increases in sexual response in normal animals at the same or higher dose levels. Pursuant to clinical trial agreements with AstraZeneca, we have conducted proof-of-principle clinical trials on the effects of a melanocortin receptor-specific compound on food intake, obesity and other metabolic parameters.

Our agreement with AstraZeneca remains in effect as long as AstraZeneca is developing a compound covered by the agreement or commercializing a product for which a royalty is owed. The agreement may be terminated by AstraZeneca at any time upon notice to us, or by either party upon notice in the event of a material breach. Upon termination by AstraZeneca without cause or by us for cause, all rights and licenses we granted to AstraZeneca terminate, but AstraZeneca remains obligated to pay royalties and milestones on compounds developed during the collaboration portion of the agreement. In the event AstraZeneca terminates the agreement because we breached the agreement, rights and licenses we granted under the agreement become permanent, with financial terms, including royalties, to be determined by arbitration.

We have received up-front and other licensing payments totaling $15 million from AstraZeneca under the agreement. We are eligible for milestone payments totaling up to $145 million, with up to $85 million contingent upon development and regulatory milestones and the balance on achievement of sales targets, plus mid to high single digit royalties on sales of approved products. AstraZeneca has responsibility for product commercialization, product discovery and development costs.

Other Melanocortin Programs. We have initiated preclinical development programs on a number of programs utilizing peptide compounds we have developed. These programs include highly selective melanocortin-1 receptor agonists for treatment of inflammation-related diseases and disorders and melanocortin-4 receptor agonists for treatment of obesity and other indications outside the sexual dysfunction field.

Natriuretic Peptide Receptor-Specific Programs

The natriuretic peptide receptor system has numerous cardiovascular functions, and therapeutic agents modulating this system may be useful in treatment of acute asthma, other pulmonary diseases, heart failure and hypertension. While the therapeutic potential of modulating this system is well appreciated, development of therapeutic agents has been difficult due, in part, to the short biological half-life of native peptide agonists.

PL-3994. PL-3994 is a synthetic mimetic of the neuropeptide hormone atrial natriuretic peptide (ANP), and is a natriuretic peptide receptor-A (NPR-A) agonist. PL-3994 is in development for treatment of acute exacerbations of asthma, heart failure and refractory hypertension. PL-3994 activates NPR-A, a receptor known to play a role in cardiovascular homeostasis. Consistent with being an NPR-A agonist, PL-3994 increases plasma cyclic guanosine monophosphate (cGMP) levels, a pharmacological response consistent with the effects of endogenous (naturally produced) natriuretic peptides on cardiovascular function and smooth muscle relaxation. PL-3994 also decreases activity of the renin-angiotensin-aldosterone system (RAAS), a hormone system that regulates blood pressure and fluid balance. The RAAS system is frequently over-activated in heart failure patients, leading to worsening of cardiovascular function.

PL-3994 is one of a number of natriuretic peptide receptor agonist compounds we have developed. PL-3994 is a synthetic molecule incorporating a novel and proprietary amino acid mimetic structure, and has an extended circulation half-life compared to endogenous ANP.

PL-3994 for Acute Exacerbations of Asthma. Research over the past two decades has demonstrated potent bronchodilator effects with both systemic and inhalation administration of natriuretic peptides. NPR-A agonism is

known to relax smooth muscles in airways and works through a pathway independent of the beta-2 adrenergic receptor. Preclinical testing demonstrated potent airway smooth muscle relaxation in guinea pig and human tissues using PL-3994, and animal studies in sensitized guinea pigs have demonstrated a bronchodilator effect with PL-3994 using both subcutaneous and inhalation administration.

Acute exacerbations of asthma, also called acute severe asthma, is an ongoing, unremitting asthma episode in which asthma symptoms do not adequately respond to initial bronchodilator therapy. Inhaled beta-2 adrenergic receptor agonists, such as albuterol, inhaled anticholinergic drugs, such as ipratropium, and systemic corticosteroids are primary treatments for episodes of acute exacerbations of asthma. Some patients with acute exacerbations of asthma become unresponsive to beta-2 adrenergic receptor agonists, significantly limiting treatment options and increasing risk. Patients who do not respond to initial therapy are at risk of severe complications. We intend to initially target PL-3994 as a treatment for those at risk unresponsive patients.

Emergency room visits and hospitalizations due to asthma have remained stable from 2001 to 2009, with almost 1.7 million emergency room visits and 440,000 hospitalizations attributed to asthma in 2006. In 2008, approximately 23.3 million Americans had asthma, with a projected 2010 economic cost in the United States of $20.7 billion, of which the largest single direct medical expenditure, $5.9 billion, is for prescription drugs.

Endogenous natriuretic peptides have a very short half-life, due primarily to degradation by neutral endopeptidase and clearance through the natriuretic peptide clearance receptor. PL-3994 is resistant to neutral endopeptidase and clears from the body much more slowly than endogenous natriuretic peptides. PL-3994 has a blood-plasma half-life of at least three hours in humans when administered by subcutaneous injection, with biological effects seen for over eight hours post-administration.

We are exploring development of an inhalation formulation of PL-3994, including preclinical inhalation toxicity and other studies that are required to start clinical trials with an inhaled formulation of PL-3994.

PL-3994 for Heart Failure. Heart failure is an illness in which the heart is unable to pump blood efficiently, and includes acutely decompensated heart failure with dyspnea (shortness of breath) at rest or with minimal activity. Endogenous natriuretic peptides have a number of beneficial effects, including vasodilation (relaxation of blood vessels), natriuresis (excretion of sodium), and diuresis (excretion of fluids).

Patients who have been admitted to the hospital with an episode of worsening heart failure have an increased risk of either death or hospital readmission in the three months following discharge. Up to 15% of patients die in this period and as many as 30% need to be readmitted to the hospital. We believe that decreasing mortality and hospital readmission in patients discharged following hospitalization for worsening heart failure is a large unmet medical need for which PL-3994 may be effective. PL-3994 could potentially be utilized as an adjunct to existing heart failure medications, and may, if successfully developed, be self-administered by patients as a subcutaneous injection following hospital discharge. We believe that PL-3994, through activation of NPR-A, may, if successful, reduce cardiac hypertrophy (increase in heart size due to disease), which is an independent risk factor for cardiovascular morbidity and mortality.

Over 5.7 million Americans suffer from heart failure, with 670,000 new cases of heart failure diagnosed each year, with disease incidence expected to increase with the aging of the American population. Despite the treatment of heart failure with multiple drugs, almost all heart failure patients will experience at least one episode of acute heart failure that requires treatment with intravenous medications in the hospital. Heart failure has tremendous human and financial costs. For 2010 the estimated direct costs in the United States for heart failure were $39.2 billion, with heart failure constituting the leading cause of hospitalization in people over 65 years of age and with over 1.1 million hospital discharges for heart failure in 2006. Heart failure is also a high mortality disease, with approximately one-half of heart failure patients dying within five years of initial diagnosis.

We have planned a repeat dose Phase 2 clinical trial in patients hospitalized with heart failure to evaluate safety profiles in patients given repeat doses of PL-3994 as well as pharmacokinetic (period to metabolize or excrete the drug) and pharmacodynamic (period of action or effect of the drug) endpoints, but do not presently intend to initiate this trial unless we reach agreement with a partner to develop PL-3994 for this indication.

Clinical Studies with PL-3994. Human clinical studies of PL-3994 commenced with a Phase 1 trial which concluded in the first quarter of calendar year 2008. This was a randomized, double-blind, placebo-controlled study in 26 healthy volunteers who received either PL-3994 or a placebo subcutaneously. The evaluations included safety, tolerability, pharmacokinetics and several pharmacodynamic endpoints, including levels of cGMP, a natural messenger nucleotide. Dosing concluded with the successful achievement of the primary endpoint of the study, a prespecified reduction in systemic blood pressure. No volunteer experienced a serious or severe adverse event. Elevations in plasma cGMP levels, increased diuresis and increased natriuresis were all observed for several hours after single subcutaneous doses.

In the second quarter of calendar year 2008, we conducted a Phase 2A trial in volunteers with controlled hypertension who were receiving one or more conventional antihypertensive medications. In this trial, which was a randomized, double-blind, placebo-controlled, single ascending dose study in 21 volunteers, the objective was to demonstrate that PL-3994 can be given safely to patients taking antihypertensive medications commonly used in heart failure and hypertension patients. Dosing concluded with the successful achievement of the primary endpoint of the study, a prespecified reduction in systemic blood pressure. No volunteer experienced a serious or severe adverse event. Elevations in plasma cGMP levels were observed for several hours after single subcutaneous doses.

Administration of PL-3994. For asthma indications we believe that inhalation administration of PL-3994 may be preferable to subcutaneous or other systemic administration. For heart failure and refractory hypertension indications we believe that subcutaneous administration of PL-3994 may be preferable. PL-3994 is well absorbed through the subcutaneous route of administration. In human studies, the pharmacokinetic and pharmacodynamic half-lives were on the order of hours, significantly longer than the comparable half-lives of endogenous natriuretic peptides. We believe that subcutaneous PL-3994, if successful, will be amenable to self-administration by patients, similar to insulin and other self-administered drugs.

Other Natriuretic Peptide Receptor-Specific Programs. We have initiated preclinical development programs on several early stage research and discovery programs in the natriuretic peptide receptor field.

Other Programs

We previously marketed NeutroSpec®, a radiolabeled monoclonal antibody product for imaging and diagnosing infection, which is the subject of a strategic collaboration agreement with the Mallinckrodt division of Covidien Ltd. In 2007 we suspended marketing, clinical trials and securing regulatory approvals of NeutroSpec, and do not anticipate conducting any substantive work or incurring substantial expenditures on NeutroSpec over the next twelve months.

Technologies We Use

We used a rational drug design approach to discover and develop proprietary peptide, peptide mimetic and small molecule agonist compounds, focusing on melanocortin and natriuretic peptide receptor systems. Computer-aided drug design models of receptors are optimized based on experimental results obtained with peptides and small molecules that we develop, supported by conformational analyses of peptides in solution utilizing nuclear magnetic resonance spectroscopy. By integrating both technologies, we believe we are developing an advanced understanding of the factors which drive agonism.

We have developed a series of proprietary technologies used in our drug development programs. One technology employs novel amino acid mimetics in place of selected amino acids. These mimetics provide the receptor-binding functions of conventional amino acids while providing structural, functional and physiochemical advantages. The amino acid mimetic technology is employed in PL-3994, our compound in development for treatment of acute exacerbations of asthma, heart failure and refractory hypertension.

Some compound series have been derived using our proprietary and patented platform technology, called MIDAS™ (Metal Ion-induced Distinctive Array of Structures). This technology employs metal ions to fix the three-dimensional configuration of peptides, forming conformationally rigid molecules that remain folded specifically in their active state. These MIDAS molecules are generally simple to synthesize, are chemically and proteolytically stable, and have the potential to be orally bioavailable. In addition, MIDAS molecules are information-rich and provide data on structure-activity relationships that may be used to design small molecule, non-peptide drugs.

Estimate of Amount Spent on Research and Development Activities

Research and development expenses were $13.8 million for the fiscal year ended June 30, 2012 (fiscal 2012) and $10.4 million for the fiscal year ended June 30, 2011 (fiscal 2011), of which $0.1 and $0.5 million, respectively, were borne by AstraZeneca pursuant to the research collaboration and license agreement.

Competition

General. Our products under development will compete on the basis of quality, performance, cost effectiveness and application suitability with numerous established products and technologies. We have many competitors, including pharmaceutical, biopharmaceutical and biotechnology companies. Furthermore, there are several well-established products in our target markets that we will have to compete against. Products using new technologies which may be competitive with our proposed products may also be introduced by others. Most of the companies selling or developing competitive products have financial, technological, manufacturing and distribution resources significantly greater than ours and may represent significant competition for us.

The pharmaceutical and biotechnology industries are characterized by extensive research efforts and rapid technological change. Many biopharmaceutical companies have developed or are working to develop products similar to ours or that address the same markets. Such companies may succeed in developing technologies and products that are more effective or less costly than any of those that we may develop. Such companies may be more successful than us in developing, manufacturing and marketing products.

We cannot guarantee that we will be able to compete successfully in the future or that developments by others will not render our proposed products under development or any future product candidates obsolete or non-competitive or that our collaborators or customers will not choose to use competing technologies or products.

Bremelanotide for Treatment of Female Sexual Dysfunction. There is competition and financial incentive to develop, market and sell drugs for the treatment of FSD, for which there is no approved drug in the United States. We are aware of one drug utilizing a testosterone transdermal patch which completed two Phase 3 efficacy trials for treatment of FSD in surgically post-menopausal women, but which did not show statistical separation from placebo in those trials. The company developing this drug has announced plans to initiate new Phase 3 efficacy trials. We are also aware of a non-hormone oral drug, flibanserin, investigated for treatment of premenopausal women with hypoactive sexual desire disorder. Development of this drug was terminated following failure of the FDA to approve the drug for marketing. However, this drug has been licensed to a third party, which intends to seek FDA approval. There are other companies reported to be developing new drugs for FSD indications, some of which may be in clinical trials in the United States or elsewhere. We are not aware of any company actively developing a melanocortin receptor agonist drug for FSD.

Melanocortin Receptor Agonists for Treatment of Erectile Dysfunction. Leading drugs approved for ED indications are PDE-5 inhibitors which target the vascular system, such as sildenafil (sold under the trade name Viagra®), vardenafil (sold under the trade name Levitra®) and tadalafil (sold under the trade name Cialis®). In addition, we are aware of other PDE-5 inhibitors under development. Other drugs approved for ED indications include alprostadil for injection (sold under the trade name Caverject Impulse® among others), which is injected directly into the penis, and alprostadil in urethral suppository format (sold under the trade name MUSE®). In addition, a variety of devices, including vacuum devices and surgical penile implants, have been approved for ED indications. We are aware of a number of companies developing new drugs for ED indications, including at least one company developing a new drug for treatment of ED not sufficiently responsive to PDE-5 inhibitors, some of which are in clinical trials in the United States and elsewhere. We are not aware of any company actively developing a melanocortin receptor agonist drug for ED.

PL-3994 for Acute Exacerbations of Asthma Indications. The asthma market is intensively competitive, with substantial competition and financial incentive to develop, market and sell drugs for treatment of asthma, with projected costs of prescription drugs of $5.9 billion in the United States in 2010. We are aware of companies developing drugs for the specific indications of either acute exacerbations of asthma or acute severe asthma, including at least one company with a drug reported to be currently in clinical trials. Certain of these drugs under development work by mechanisms of action different from the mechanisms of action of currently approved products. In addition, a number of clinical trials are conducted by hospitals, research institutes and others exploring various methods and combinations of drugs to treat acute exacerbations of asthma. There are a number of drugs and therapies currently used to treat acute exacerbations of asthma, including administration of oral or intravenous systemic steroids, use of oxygen or heliox, a mixture of helium and oxygen, nebulized short-acting beta-2 adrenergic receptor agonists, intravenous or nebulized anticholinergic agents and, for patients in or approaching respiratory arrest, intubation and mechanical ventilation. However, each of these drugs or therapies has recognized limitations or liabilities, and we believe that there remains an unmet medical need for a safe and effective treatment for acute exacerbations of asthma. We are not aware of any other company actively developing a drug to treat asthma using a natriuretic peptide receptor pathway.

PL-3994 for Heart Failure Indications. Nesiritide (sold under the trade name Natrecor®), a recombinant human B-type natriuretic peptide drug, is marketed in the United States by Scios Inc., a Johnson & Johnson company. Nesiritide is approved for treatment of acutely decompensated congestive heart failure patients who have dyspnea at rest or with minimal activity. Other peptide drugs, including carperitide, a recombinant human atrial natriuretic peptide drug, and ularitide, a synthetic form of urodilatin, a naturally occurring human natriuretic peptide related to atrial natriuretic peptide, have been investigated for treatment of congestive heart failure, but are not believed to be in active

development in the United States. We are aware of other companies developing intravenously administered natriuretic peptide drugs, with at least one reported to be in Phase 2 clinical trials for acute heart failure. One product is under investigation for continuous and extended infusion through a subcutaneous pump. In addition, there are a number of approved drugs and drugs in development for treatment of heart failure through mechanisms or pathways other than agonism of NPR-A.

Obesity. There are several FDA-approved drugs and medical devices for the treatment of obesity, and a large number of products in clinical development by other companies, including products which target melanocortin receptors. Clinical trials for obesity are lengthy, time-consuming and expensive. See the discussion under the heading “We do not control the development of compounds licensed to third parties and, as a result, we may not realize a significant portion of the potential value of any such license arrangements” in Item 1A, “Risk Factors” in this Annual Report.

Patents and Proprietary Information

Patent Protection. Our success will depend in substantial part on our ability to obtain, defend and enforce patents, maintain trade secrets and operate without infringing upon the proprietary rights of others, both in the United States and abroad. We own a number of issued United States patents and have pending United States patent applications, many with issued or pending counterpart patents in selected foreign countries. We seek patent protection for our technologies and products in the United States and those foreign countries where we believe patent protection is commercially important.

We own two issued United States patents claiming the bremelanotide substance; issued patents claiming the bremelanotide substance in Japan, Mexico, Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Greece, Ireland, Korea, Luxembourg, Monaco, Netherlands, Portugal, Spain, Sweden, Switzerland, United Kingdom, Italy, Australia and New Zealand; and pending patent applications claiming the bremelanotide substance in Brazil and Canada. The issued United States patents have a term until 2020, which term may be subject to extension for a maximum period of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process, pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Amendments). Whether we will be able to obtain patent term extensions under the Hatch-Waxman Amendments and the length of the extension to which we may be entitled cannot be determined until the FDA approves for marketing, if ever, a product in which bremelanotide is the active ingredient. In addition, the claims of issued patents covering bremelanotide may not provide meaningful protection. Further, third parties may challenge the validity or scope of any issued patent.

We also own an issued United States patent claiming non-oral administration of bremelanotide in combination with oral administration of a PDE-5 inhibitor. This patent has a term until 2025. However, this patent would apply only if we develop bremelanotide for use in combination therapy with a PDE-5 inhibitor. If we obtain regulatory approval for bremelanotide for use in combination therapy with a PDE-5 inhibitor, which may never occur, then the patent term may be subject to extension under the Hatch-Waxman Amendments, but we cannot presently evaluate the duration of any potential patent term extension.

We own patent applications on one class of alternative melanocortin receptor-specific peptides for treatment of sexual dysfunction which are pending in the United States, Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico and South Africa and before the European and Eurasian patent offices. If any patent issues in the United States, the presumptive term will be until 2029. We also own patent applications for a second class of alternative melanocortin receptor-specific peptides for treatment of sexual dysfunction which are pending in the United States, Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico and South Africa and before the European and Eurasian patent offices. If any patent issues in the United States, the presumptive term will be until 2030. Until one or more product candidates covered by a claim of one of these patent applications are developed for commercialization, which may never occur, we cannot evaluate the duration of any potential patent term extension under the Hatch-Waxman Amendments.

We own patent applications on two classes of highly selective melanocortin-1 receptor agonist peptides for treatment of inflammation-related diseases and disorders and related indications which are pending in the United States, Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico and South Africa and before the European and Eurasian patent offices. If any patent issues in the United States, the presumptive term will be until 2030. Until one or more product candidates covered by a claim of one of these patent applications are developed for commercialization, which may never occur, we cannot evaluate the duration of any potential patent term extension under the Hatch-Waxman Amendments.

We own an issued United States patent claiming the PL-3994 substance and other natriuretic peptide receptor agonist compounds that we have developed and an issued United States patent claiming a precursor molecule to the PL-3994

substance, both of which have a term until 2027. Patent applications claiming the PL-3994 substance and other compounds, including precursor molecules, are pending in Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico, Philippines and South Africa and before the European and Eurasian patent offices. We do not know the full scope of patent coverage we will obtain, or whether any patents will issue other than the United States patent claiming PL-3994 and the United States patent claiming a precursor molecule. We also own a patent application under the Patent Cooperation Treaty claiming use of PL-3994 for treatment of airway diseases, including asthma, and we intend to continue prosecution only in the United States. Until one or more product candidates covered by a claim of the issued patents or one of these patent applications are developed for commercialization, which may never occur, we cannot evaluate the duration of any potential patent term extension under the Hatch-Waxman Amendments.

We additionally have twenty-seven issued United States patents on melanocortin receptor specific peptides and small molecules, but we are not actively developing any product candidate covered by a claim of any of these patents or applications.

Under our research collaboration and license agreement with AstraZeneca, AstraZeneca is responsible for prosecution of licensed patent applications and maintenance of issued patents in the United States and other countries. AstraZeneca is prosecuting a patent application before the European and Eurasian patent offices and in the United States, Argentina, Australia, Canada, China, Cuba, the Dominican Republic, Israel, Mexico, Peru, Singapore, South Korea, Taiwan and Uruguay, among others, in its name resulting from its collaboration with us. Our employees are inventors and royalties would be payable under our agreement with AstraZeneca if a compound covered by a claim of this application is developed for commercialization. If any patent issues in the United States, the presumptive term will be until 2030. This patent application has not been examined, and we do not know the scope of patent claims that will be allowed, or whether any patents will issue. Additionally, until one or more compounds subject to the agreement with AstraZeneca are developed for commercialization, which may never occur, we cannot evaluate the duration of any potential patent term extension under the Hatch-Waxman Amendments.

In the event that a third party has also filed a patent application relating to an invention we claimed in a patent application, we may be required to participate in an interference proceeding adjudicated by the United States Patent and Trademark Office to determine priority of invention. The possibility of an interference proceeding could result in substantial uncertainties and cost, even if the eventual outcome is favorable to us. An adverse outcome could result in the loss of patent protection for the subject of the interference, subjecting us to significant liabilities to third parties, the need to obtain licenses from third parties at undetermined cost, or requiring us to cease using the technology.

Future Patent Infringement. We do not know for certain that our commercial activities will not infringe upon patents or patent applications of third parties, some of which may not even have been issued. Although we are not aware of any valid United States patents which are infringed by bremelanotide or PL-3994, we cannot exclude the possibility that such patents might exist or arise in the future. We may be unable to avoid infringement of any such patents and may have to seek a license, defend an infringement action, or challenge the validity of such patents in court. Patent litigation is costly and time consuming. If such patents are valid and we do not obtain a license under any such patents, or we are found liable for infringement, we may be liable for significant monetary damages, may encounter significant delays in bringing products to market, or may be precluded from participating in the manufacture, use or sale of products or methods of treatment covered by such patents.

Proprietary Information. We rely on proprietary information, such as trade secrets and know-how, which is not patented. We have taken steps to protect our unpatented trade secrets and know-how, in part through the use of confidentiality and intellectual property agreements with our employees, consultants and certain contractors. If our employees, scientific consultants, collaborators or licensees develop inventions or processes independently that may be applicable to our product candidates, disputes may arise about the ownership of proprietary rights to those inventions and processes. Such inventions and processes will not necessarily become our property, but may remain the property of those persons or their employers. Protracted and costly litigation could be necessary to enforce and determine the scope of our proprietary rights.

If trade secrets are breached, our recourse will be solely against the person who caused the secrecy breach. This might not be an adequate remedy to us because third parties other than the person who causes the breach will be free to use the information without accountability to us. This is an inherent limitation of the law of trade secret protection.

Governmental Regulation

The FDA, comparable agencies in other countries and state regulatory authorities have established regulations and guidelines which apply to, among other things, the clinical testing, manufacturing, safety, efficacy, labeling, storage,

record keeping, advertising, promotion, marketing and distribution of our proposed products. Noncompliance with applicable requirements can result in fines, recalls or seizures of products, total or partial suspension of production, refusal of the regulatory authorities to approve marketing applications, withdrawal of approvals and criminal prosecution.

Before a drug product is approved by the FDA for commercial marketing, three phases of human clinical trials are usually conducted to test the safety and effectiveness of the product. Phase 1 clinical trials most typically involve testing the drug on a small number of healthy volunteers to assess the safety profile of the drug at different dosage levels. Phase 2 clinical trials, which may also enroll a relatively small number of patient volunteers, are designed to further evaluate the drug's safety profile and to provide preliminary data as to the drug's effectiveness in humans. Phase 3 clinical trials consist of larger, well-controlled studies that may involve several hundred or thousand patient volunteers representing the drug's targeted population. During any of these phases, the FDA can place the clinical trial on clinical hold, or temporarily or permanently stop the clinical trials for a variety of reasons, principally for safety concerns.

After approving a product for marketing, the FDA may require post-marketing testing, including extensive Phase 4 studies, and surveillance to monitor the safety and effectiveness of the product in general use. The FDA may withdraw product approvals if compliance with regulatory standards is not maintained or if problems occur following initial marketing. In addition, the FDA may impose restrictions on the use of a drug that may limit its marketing potential. The failure to comply with applicable regulatory requirements in the United States and in other countries in which we conduct development activities could result in a variety of fines and sanctions, such as warning letters, product recalls, product seizures, suspension of operations, fines and civil penalties or criminal prosecution.

In addition to obtaining approval of a New Drug Application (an NDA) from the FDA for any of our proposed products, any facility that manufactures such a product must comply with current good manufacturing practices (GMPs). This means, among other things, that the drug manufacturing establishment must be registered with, and subject to inspection by, the FDA. Foreign manufacturing establishments must also comply with GMPs and are subject to periodic inspection by the FDA or by corresponding regulatory agencies in such other countries under reciprocal agreements with the FDA. In complying with standards established by the FDA, manufacturing establishments must continue to expend time, money and effort in the areas of production and quality control to ensure full technical compliance. We will use contract manufacturing establishments, in the United States or in foreign countries, to manufacture our proposed products, and will depend on those establishments to comply with GMPs and other regulatory requirements.

Third-Party Reimbursements

Successful sales of our proposed products in the United States and other countries may depend, in large part, on the availability of adequate reimbursement from third-party payors such as governmental entities, managed care organizations, health maintenance organizations (HMOs) and private insurance plans. Reimbursement by a third-party payor may depend on a number of factors, including the payor's determination that the product has been approved by the FDA for the indication for which the claim is being made, that it is neither experimental nor investigational, and that the use of the product is safe and efficacious, medically necessary, appropriate for the specific patient and cost effective. Since reimbursement by one payor does not guarantee reimbursement by another, we or our licensees may be required to seek approval from each payor individually. Seeking such approvals is a time-consuming and costly process. Third-party payors routinely limit the products that they will cover and the amount of money that they will pay and, in many instances, are exerting significant pressure on medical suppliers to lower their prices. There is significant uncertainty concerning third-party reimbursement for the use of any pharmaceutical product incorporating new technology and we are not sure whether third-party reimbursement will be available for our proposed products once approved, or that the reimbursement, if obtained, will be adequate. There are no approved products for treating FSD, and thus is significant uncertainty concerning the extent and scope of third-party reimbursement for products treating FSD. Based on third-party reimbursement for approved products treating ED, we believe reimbursement will be limited for bremelanotide for treatment of FSD, assuming the product is approved by the FDA. Less than full reimbursement by governmental and other third-party payors for our proposed products may adversely affect the market acceptance of bremelanotide and other of our proposed products. Further, healthcare reimbursement systems vary from country to country, and we are not sure whether third-party reimbursement will be made available for our

proposed products under any other reimbursement system.

Manufacturing and Marketing

To be successful, our proposed products will need to be manufactured in commercial quantities under GMPs prescribed by the FDA and at acceptable costs. We do not have the facilities to manufacture any of our proposed products under GMPs. We intend to rely on collaborators, licensees or contract manufacturers for the commercial manufacture of our proposed products.

Our bremelanotide product candidate is a synthetic peptide. While the production process involves well-established technology, there are few manufacturers capable of scaling up to commercial quantities under GMPs at acceptable costs. We have identified one third-party manufacturer for the production of bremelanotide, and have validated manufacturing of the bremelanotide drug substance under GMPs with that manufacturer. However, we have not negotiated a long-term supply agreement with the third-party manufacturer, and may not be able to enter into a supply agreement on acceptable terms, if at all.

Our bremelanotide product candidate will be a combination product, incorporating both the bremelanotide drug substance and a delivery device. We will rely on a third-party manufacturer to make the delivery device and the final product combination product. We have not yet selected a delivery device. Once a delivery device is selected, we will need to negotiate a long-term supply and manufacturing agreement, and may not be able to enter into such an agreement on acceptable terms, if at all.

Our PL-3994 product candidate is a peptide mimetic molecule, incorporating a proprietary amino acid mimetic structure and amino acids. We have identified a manufacturer which made the product in quantities sufficient for Phase 1 and some anticipated Phase 2 clinical trials, and are in the process of evaluating commercial-scale manufacturers. Scaling up to commercial quantities may involve production, purification, formulation and other problems not present in the scale of manufacturing done to date.

Certain of our melanocortin receptor agonist product candidates are synthetic peptides, which we have primarily manufactured in-house. We have not contracted with a third-party manufacturer to produce these synthetic peptides for either clinical trials or commercial purposes. While the production process involves well-established technology, there are few manufacturers capable of scaling up to commercial quantities under GMPs at acceptable costs. Additionally, scaling up to commercial quantities may involve production, purification, formulation and other problems not present in the scale of manufacturing done to date.

The failure of any manufacturer or supplier to comply with FDA GMPs, or to supply the drug substance and services as agreed, would force us to seek alternative sources of supply and could interfere with our ability to deliver product on a timely and cost effective basis or at all. Establishing relationships with new manufacturers or suppliers, any of whom must be FDA-approved, is a time-consuming and costly process.

Product Liability and Insurance

Our business may be affected by potential product liability risks which are inherent in the testing, manufacturing, marketing and use of our proposed products. We have liability insurance providing up to $10 million coverage in the aggregate as to certain clinical trial risks.

Employees

As of September 7, 2012, we employed 16 persons full time, of whom 9 are engaged in research and development activities and 7 are engaged in administration and management. While we have been successful in attracting skilled and experienced scientific personnel, competition for personnel in our industry is intense. None of our employees are covered by a collective bargaining agreement. All of our employees have executed confidentiality and intellectual property agreements. We consider relations with our employees to be good.

We rely on contractors and scientific consultants to work on specific research and development programs. We also rely on independent organizations, advisors and consultants to provide services, including aspects of manufacturing, testing, preclinical evaluation, clinical management, regulatory strategy and market research. Our independent advisors, contractors and consultants sign agreements that provide for confidentiality of our proprietary information and that we have the rights to any intellectual property developed while working for us.

Item 1A. Risk Factors.

Risks Relating to Our Company

We will continue to incur substantial losses over the next few years and we may never become profitable.

We have never been profitable and we may never become profitable. As of June 30, 2012, we had an accumulated deficit of $239.2 million. We expect to incur additional losses as we continue our development of bremelanotide, PL-3994 and other product candidates. Unless and until we receive approval from the FDA or other equivalent regulatory authorities outside the United States, we cannot sell our products and will not have product revenues from them. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from reimbursements and other contract revenue under collaborative development agreements, existing cash balances and outside sources of financing, which may not be available on acceptable terms, if at all.

We will need to continue to raise funds in the future, and funds may not be available on acceptable terms, or at all.

As of June 30, 2012, and giving effect to the private placement with net proceeds of $34.5 million which closed on July 3, 2012, we had cash and cash equivalents of $38.3 million, with current liabilities of $3.5 million. We believe we have sufficient currently available working capital to fund our currently planned operations through at least calendar year 2013, but our currently available working capital is not sufficient to complete required clinical trials for any of our product candidates. We will need additional funding to complete required clinical trials and, assuming those clinical trials are successful, as to which there can be no assurance, complete submission of required regulatory applications to the FDA for any of our product candidates. We expect that the Phase 3 bremelanotide clinical trial program for FSD will require significant additional resources and capital.

We do not have any source of significant recurring revenue, and must depend on financing or partnering to sustain our operations. We may raise additional funds through public or private equity financings, debt financings, collaborative arrangements on our product candidates or other sources. However, additional funding may not be available on acceptable terms, or at all. To obtain additional funding, we may need to enter into arrangements that require us to develop only certain of our product candidates or relinquish rights to certain technologies, product candidates and/or potential markets.

If we are unable to raise sufficient additional funds when needed, we may be required to curtail operations significantly, cease clinical trials and further decrease staffing levels. We may seek to license, sell or otherwise dispose of our product candidates, technologies and contractual rights, including rights under our research collaboration and license agreement with AstraZeneca, on the best possible terms available. Even if we are able to license, sell or otherwise dispose of our product candidates, technologies and contractual rights, it is likely to be on unfavorable terms and for less value than if we had the financial resources to develop or otherwise advance our product candidates, technologies and contractual rights ourselves.

We have a limited operating history upon which to base an investment decision.

Our operations are primarily focused on acquiring, developing and securing our proprietary technology, conducting preclinical and clinical studies and formulating and manufacturing on a small-scale basis our principal product candidates. These operations provide a limited basis for stockholders to assess our ability to commercialize our product candidates.

We have not yet demonstrated our ability to perform the functions necessary for the successful commercialization of any of our current product candidates. The successful commercialization of our product candidates will require us to perform a variety of functions, including:

- continuing to conduct preclinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products, or having third parties formulate and manufacture products;
- post-approval monitoring and surveillance of our products;
- conducting sales and marketing activities, either alone or with a partner; and
- obtaining additional capital.

If we are unable to obtain regulatory approval of any of our product candidates, to successfully commercialize any products for which we receive regulatory approval or to obtain additional capital, we may not be able to recover our investment in our development efforts.

We may not be able to obtain regulatory approval of bremelanotide for FSD even if the product is effective in treating FSD.

Approval of bremelanotide for treatment of FSD in premenopausal women requires determination by the FDA that the product is both safe and effective. Increases in blood pressure observed in some patients receiving nasally administered bremelanotide was a significant factor leading us to discontinue work on nasally administered bremelanotide for sexual dysfunction. Studies we have conducted with subcutaneously administered bremelanotide suggest that transient elevations of blood pressure are dependent on both the specific patient population and the dose administered. Based on these studies, we believe that bremelanotide will be effective in treating FSD at doses that do not result in unacceptable increases in blood pressure or other unacceptable adverse events. However, results obtained in later phases of clinical trials, including our Phase 2B clinical trial and any future Phase 3 clinical trial, may be inconsistent with results obtained in earlier studies, and may demonstrate an unacceptable safety profile. It is also possible that safety or efficacy results obtained in later phases of clinical trials will be inconclusive. It is not possible to predict, with any assurance, whether the FDA will approve bremelanotide for any indications. The FDA may deny or delay approval of any application for bremelanotide if the FDA determines that the clinical data do not adequately establish the safety of the drug even if efficacy is established. Bremelanotide could take a significantly longer time to obtain approval than we expect and it may never gain approval. If regulatory approval of bremelanotide is delayed or never obtained, our business and our liquidity would be adversely affected.

Development and commercialization of our product candidates involves a lengthy, complex and costly process, and we may never successfully develop or commercialize any product.

Our product candidates are at various stages of research and development, will require regulatory approval, and may never be successfully developed or commercialized. Our product candidates will require significant further research, development and testing before we can seek regulatory approval to market and sell them.

We must demonstrate that our product candidates are safe and effective for use in patients in order to receive regulatory approval for commercial sale. Preclinical studies in animals, using various doses and formulations, must be performed before we can begin human clinical trials. Even if we obtain favorable results in the preclinical studies, the results in humans may be different. Numerous small-scale human clinical trials may be necessary to obtain initial data on a product candidate's safety and efficacy in humans before advancing to large-scale human clinical trials. We face the risk that the results of our trials in later phases of clinical trials may be inconsistent with those obtained in earlier phases. Adverse or inconclusive results could delay the progress of our development programs and may prevent us from filing for regulatory approval of our product candidates. Additional factors that can cause delay or termination of our human clinical trials include:

- the availability of sufficient capital to sustain operations and clinical trials;
- timely completion of clinical site protocol approval and obtaining informed consent from subjects;
- the rate of patient enrollment in clinical studies;
- adverse medical events or side effects in treated patients; and
- lack of effectiveness of the product being tested.

You should evaluate us in light of these uncertainties, delays, difficulties and expenses commonly experienced by early stage biopharmaceutical companies, as well as unanticipated problems and additional costs relating to:

- product approval or clearance;
- regulatory compliance;
- good manufacturing practices;
- intellectual property rights;
- product introduction; and
- marketing and competition.

The regulatory approval process is lengthy, expensive and uncertain, and may prevent us from obtaining the approvals we require.

Government authorities in the United States and other countries extensively regulate the advertising, labeling, storage, record-keeping, safety, efficacy, research, development, testing, manufacture, promotion, marketing and distribution of drug products. Drugs are subject to rigorous regulation by the FDA and similar regulatory bodies in other countries. The steps ordinarily required by the FDA before a new drug may be marketed in the United States include:

- completion of non-clinical tests including preclinical laboratory and formulation studies and animal testing and toxicology;

- submission to the FDA of an IND application, which must become effective before clinical trials may begin;

- performance of adequate and well-controlled Phase 1, 2 and 3 human clinical trials to establish the safety and efficacy of the drug for each proposed indication;

- submission to the FDA of an NDA;

- FDA review and approval of the NDA before any commercial marketing or sale; and

- Compliance with post-approval commitments and requirements.

Satisfaction of FDA pre-market approval requirements for new drugs typically takes a number of years and the actual time required for approval may vary substantially based upon the type, complexity and novelty of the product or disease. The results of product development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA. The NDA also must contain extensive manufacturing information. Once the submission has been accepted for filing, the FDA generally has ten months to review the application and respond to the applicant. The review process is often significantly extended by FDA requests for additional information or clarification. Success in early stage clinical trials does not assure success in later stage clinical trials. Data obtained from clinical trials is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved, but the FDA is not bound by the recommendation of the advisory committee. The FDA may deny or delay approval of applications that do not meet applicable regulatory criteria or if the FDA determines that the clinical data do not adequately establish the safety and efficacy of the drug. Therefore, our proposed products could take a significantly longer time than we expect or may never gain approval. If regulatory approval is delayed or never obtained, our business and our liquidity would be adversely affected.

Upon approval, a product candidate may be marketed only in those dosage forms and for those indications approved by the FDA. Once approved, the FDA may withdraw the product approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the marketplace. In addition, the FDA may require post-marketing studies, referred to as Phase 4 studies, to monitor the approved products in a larger number of patients than were required for product approval and may limit further marketing of the product based on the results of these post-market studies. The FDA has broad post-market regulatory and enforcement powers, including the ability to seek injunctions, levy fines and civil penalties, criminal prosecution, withdraw approvals and seize products or request recalls.

If regulatory approval of any of our product candidates is granted, it will be limited to certain disease states or conditions. Adverse experiences with the product must be reported to the FDA and could result in the imposition of market restriction through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

Outside the United States, our ability to market our product candidates will also depend on receiving marketing authorizations from the appropriate regulatory authorities. The foreign regulatory approval process generally includes all of the risks associated with FDA approval described above. The requirements governing the conduct of clinical trials and marketing authorization vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, although within the European Community, or EC, registration procedures are available to companies wishing to market a product to more than one EC member state. If the regulatory authority is satisfied that adequate evidence of safety, quality and efficiency has been presented, a marketing authorization will be granted. If we do not obtain, or experience difficulties in obtaining, such marketing authorizations, our business and liquidity may be adversely affected.

If any approved product does not achieve market acceptance, our business will suffer.

Regulatory approval for the marketing and sale of any of our product candidates does not assure the product's commercial success. Any approved product will compete with other products manufactured and marketed by major pharmaceutical and other biotechnology companies. The degree of market acceptance of any such product will depend on a number of factors, including:

- perceptions by members of the healthcare community, including physicians, about its safety and effectiveness;
- cost-effectiveness relative to competing products and technologies;

- availability of reimbursement for our products from third party payors such as health insurers, health maintenance organizations and government programs such as Medicare and Medicaid; and

- advantages over alternative treatment methods.

If any approved product does not achieve adequate market acceptance, our business, financial condition and results of operations will be adversely affected.

We rely on third parties to conduct clinical trials for our product candidates and their failure to timely perform their obligations could significantly harm our product development.

We rely on outside scientific collaborators such as researchers at clinical research organizations and universities in certain areas that are particularly relevant to our research and product development plans, such as the conduct of clinical trials and associated tests. There is competition for these relationships, and we may not be able to maintain our relationships with them on acceptable terms. These outside collaborators generally may terminate their engagements with us at any time. As a result, we can control their activities only within certain limits, and they will devote only a certain amount of their time to conduct research on our product candidates and develop them. If they do not successfully carry out their duties under their agreements with us, fail to inform us if these trials fail to comply with clinical trial protocols or fail to meet expected deadlines, our ability to develop our product candidates and obtain regulatory approval on a timely basis, if at all, may be adversely affected.

Our drug development programs depend on contract research organizations and other third parties over whom we have no control.

We have limited research or development staff and do not have dedicated research or development facilities, and depend on third parties, including independent contractors and preclinical contract research organizations, to conduct preclinical studies under agreements with us. These collaborators are not our employees, and we have limited control over the resources that they devote to our programs. These collaborators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. These collaborators generally may terminate their engagements with us at any time. As a result, we can control their activities only within certain limits, and they will devote only a certain amount of their time to conduct research on our product candidates. If they do not successfully carry out their duties under their agreements with us, fail to inform us if these studies fail to comply with agreed protocols or fail to meet expected deadlines, our ability to develop our product candidates and obtain regulatory approval on a timely basis, if at all, may be adversely affected.

Production and supply of our product candidates depend on contract manufacturers over whom we have no control.

We do not have the facilities to manufacture bremelanotide, PL-3994, melanocortin receptor agonist compounds or our other potential products. Our contract manufacturers must perform these manufacturing activities in a manner that complies with FDA regulations. Our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection. The manufacturers of approved products and their manufacturing facilities will be subject to continual review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing regulatory requirements, including the FDA's GMPs regulations. Failure of third-party manufacturers to comply with GMPs or other FDA requirements may result in enforcement action by the FDA. Failure to conduct their activities in compliance with FDA regulations could delay our development programs or negatively impact our ability to receive FDA approval of our potential products or continue marketing if they are approved. Establishing relationships with new suppliers, who must be FDA-approved, is a time-consuming and costly process.

We have no experience in marketing, distributing and selling products and will substantially rely on our marketing partners to provide these capabilities.

We are developing bremelanotide for FSD and may develop other melanocortin receptor agonist compounds for sexual dysfunction and other indications and PL-3994 for the treatment of asthma, heart failure and other indications. We do not have marketing partners for any of these products. If any of these products are approved by the FDA or other regulatory authorities, we must either develop marketing, distribution and selling capacity and expertise, which will be costly and time consuming, or enter into agreements with other companies to provide these capabilities. We may not be able to enter into suitable agreements on acceptable terms, if at all.

We do not control the development of compounds licensed to third parties and, as a result, we may not realize a significant portion of the potential value of any such license arrangements.

Under our research collaboration and license agreement with AstraZeneca for our melanocortin-based therapeutic compounds for obesity, diabetes and related metabolic syndrome, we have no direct control over the development of compounds and have only limited, if any, input on the direction of development efforts. Based on a serious adverse event, AstraZeneca has decided to discontinue development of AZD2820, a subcutaneously-administered peptide melanocortin-4 receptor partial agonist. AstraZeneca has a number of collaboration compounds in various stages of preclinical testing, and remains committed to the continued advancement of melanocortin agonists for treatment of obesity. If the results of further development efforts are negative or inconclusive, AstraZeneca may decide to abandon further development of this program, including terminating the agreement, by giving us notice of termination. Because much of the potential value of the license arrangement with AstraZeneca is contingent upon the successful development and commercialization of the licensed technology, the ultimate value of this license will depend on the efforts of AstraZeneca. If AstraZeneca does not succeed in developing the licensed technology for any reason, or elects to discontinue the development of this program, we may be unable to realize the potential value of this arrangement. Compounds developed during the collaboration phase of our agreement with AstraZeneca are subject to the same payment terms as licensed compounds, but intellectual property relating to collaboration compounds is owned by AstraZeneca. If AstraZeneca does not succeed in developing collaboration compounds, we will not realize any value with respect to those compounds.

If the market opportunities for bremelanotide and our other products in development are smaller than we anticipate, then our future revenues and business may be adversely affected.

There are no FDA approved products for treatment of FSD, and thus the size and other parameters relating to the market are not known. The market opportunity for bremelanotide may be smaller than we anticipate. If it is smaller, it may be difficult for us to find marketing partners for bremelanotide, and our ability to generate bremelanotide revenue and business may be adversely affected. This is also true with respect to PL-3994 and other products in development.

Competing products and technologies may make our proposed products noncompetitive.

There are other products being developed for FSD, including a product currently in Phase 3 clinical trials. There is competition to develop drugs for treatment of FSD in both premenopausal and postmenopausal patients. Our bremelanotide drug product is intended to be administered by subcutaneous injection, and a drug product for the same indication which utilizes another route of administration, such as a conventional oral drug product, may make subcutaneous bremelanotide noncompetitive.

There are three oral FDA-approved PDE-5 inhibitor drugs for the treatment of ED, other approved products and devices for ED, and other products in development for treatment of ED, including products in clinical trials. There is competition to develop drugs for ED in patients non-responsive to PDE-5 inhibitor drugs, and to develop drugs for treatment of FSD.

There are a large number of products approved for use in asthma, and a number of other products being developed for treatment of acute exacerbations of asthma, including products in clinical trials. There is intense competition to develop drugs for treatment of acute exacerbations of asthma.

We are aware of one recombinant natriuretic peptide product for acutely decompensated congestive heart failure approved and marketed in the United States, and another recombinant natriuretic peptide product approved and marketed in Japan. Clinical trials on other natriuretic peptide products are being conducted in the United States. In addition, other products for treatment of heart failure are either currently being marketed or in development.

The biopharmaceutical industry is highly competitive. We are likely to encounter significant competition with respect to bremelanotide, other melanocortin receptor agonist compounds and PL-3994. Most of our competitors have substantially greater financial and technological resources than we do. Many of them also have significantly greater experience in research and development, marketing, distribution and sales than we do. Accordingly, our competitors may succeed in developing, marketing, distributing and selling products and underlying technologies more rapidly than we can. These competitive products or technologies may be more effective and useful or less costly than bremelanotide, other melanocortin receptor agonist compounds or PL-3994. In addition, academic institutions, hospitals, governmental agencies and other public and private research organizations are also conducting research and may develop competing products or technologies on their own or through strategic alliances or collaborative arrangements.

Our ability to achieve revenues from the sale of our products in development will depend, in part, on our ability to obtain adequate reimbursement from Medicare, Medicaid, private insurers and other healthcare payers.

Our ability to successfully commercialize our products in development will depend, in significant part, on the extent to which we or our marketing partners can obtain reimbursement for our products and also reimbursement at appropriate levels for the cost of our products. Obtaining reimbursement from governmental payers, insurance companies, HMOs and other third-party payers of healthcare costs is a time-consuming and expensive process. There is no guarantee that our products will ultimately be reimbursed. There is significant uncertainty concerning third-party reimbursement for the use of any pharmaceutical product incorporating new technology and we are not sure whether third-party reimbursement will be available for our proposed products once approved, or that the reimbursement, if obtained, will be adequate. There are no approved products for treating FSD, and thus is significant uncertainty concerning the extent and scope of third-party reimbursement for products treating FSD. If we are able to obtain reimbursement, continuing efforts by governmental and third party payers to contain or reduce costs of healthcare may adversely affect our future revenues and ability to achieve profitability. Third-party payers are increasingly challenging the prices charged for diagnostic and therapeutic products and related services. Reimbursement from governmental payers is subject to statutory and regulatory changes, retroactive rate adjustments, administrative rulings and other policy changes, all of which could materially decrease the range of products for which we are reimbursed or the rates of reimbursement by government payers. In addition, recent legislation reforming the healthcare system may result in lower prices or the actual inability of prospective customers to purchase our products in development. The cost containment measures that healthcare payers and providers are instituting and the effect of any healthcare reform could materially and adversely affect our ability to operate profitably. Furthermore, even if reimbursement is available, it may not be available at price levels sufficient for us to realize a positive return on our investment.

If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish.

Our success, competitive position and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We cannot predict:

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- if and when patents will be issued;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; and
- whether we will need to initiate litigation or administrative proceedings, which may be costly whether we win or lose.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;

- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings, which may be costly whether we win or lose, and which could result in a substantial diversion of our management resources.

If we are unable to keep our trade secrets confidential, our technologies and other proprietary information may be used by others to compete against us.

In addition to our reliance on patents, we attempt to protect our proprietary technologies and processes by relying on trade secret laws and agreements with our employees and other persons who have access to our proprietary information. These agreements and arrangements may not provide meaningful protection for our proprietary technologies and processes in the event of unauthorized use or disclosure of such information. In addition, our competitors may independently develop substantially equivalent technologies and processes or gain access to our trade secrets or technology, either of which could materially and adversely affect our competitive position.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entails an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products or cease clinical trials. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with corporate collaborators. We currently carry liability insurance as to certain clinical trial risks. We, or any corporate collaborators, may not in the future be able to obtain insurance at a reasonable cost or in sufficient amounts, if at all. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

We are highly dependent on our management team, senior staff professionals and third-party contractors and consultants, and the loss of their services could materially adversely affect our business.

We rely on our relatively small management team and staff as well as various contractors and consultants to provide critical services. Our ability to execute our bremelanotide clinical programs and our preclinical programs on an inhaled formulation of PL-3994 and a new peptide drug candidates for sexual dysfunction and other indications depends on our continued retention and motivation of our management and senior staff professionals, including executive officers and senior members of product development and management who possess significant technical expertise and experience and oversee our development programs. If we lose the services of existing key personnel, our development programs could be adversely affected if suitable replacement personnel are not recruited quickly. Our success also depends on our ability to develop and maintain relationships with contractors, consultants and scientific advisors.

There is competition for qualified personnel, contractors and consultants in the pharmaceutical industry, which makes it difficult to attract and retain the qualified personnel, contractors and consultants necessary for the development and growth of our business.

Anti-takeover provisions of Delaware law and our charter documents may make potential acquisitions more difficult and could result in the entrenchment of management.

We are incorporated in Delaware. Anti-takeover provisions of Delaware law and our charter documents may make a change in control or efforts to remove management more difficult. Also, under Delaware law, our board of directors may adopt additional anti-takeover measures. Under Section 203 of the Delaware General Corporation Law, a corporation may not engage in a business combination with an “interested stockholder” for a period of three years after the date of the transaction in which the person first becomes an “interested stockholder,” unless the business combination is approved in a prescribed manner.

Pursuant to approval by our stockholders at the annual meeting of stockholders held on May 11, 2011, we increased our authorized common stock from 40,000,000 to 100,000,000. We are seeking an increase in our authorized common stock to 200,000,000 shares, and have called a special meeting of stockholders for September 27, 2012 at which this matter will be voted on. To the extent that we sell newly authorized shares, this could have the effect of making it more difficult for a third party to acquire a majority of our outstanding voting stock.

Our charter authorizes us to issue up to 10,000,000 shares of preferred stock and to determine the terms of those shares of stock without any further action by our stockholders. If we exercise this right, it could be more difficult for a third party to acquire a majority of our outstanding voting stock.

In addition, our equity incentive plans generally permit us to accelerate the vesting of options and other stock rights granted under these plans in the event of a change of control. If we accelerate the vesting of options or other stock rights, this action could make an acquisition more costly.

The application of these provisions could have the effect of delaying or preventing a change of control, which could adversely affect the market price of our common stock.

Risks Relating to Obligations in Our 2012 Private Financing

Our ability to enter into debt or equity financings is contractually limited for a period under agreements relating to our 2012 private placement of 3,873,000 shares of our common stock and warrants to purchase an aggregate of up to 67,476,531 shares of our common stock.

Under the purchase agreement and form of warrants for our 2012 private placement which closed on July 3, 2012, we cannot offer, sell or grant any of our equity securities, other than to employees, consultants, officers or directors under an approved stock plan, or enter into any debt placement except in limited circumstances, until the later of September 1, 2013 and the date our stockholders vote to increase the authorized number of shares of our common stock, or if earlier, the date no Series B 2012 warrants remain outstanding. We do not anticipate needing to raise additional funds prior to September 1, 2013 through the sale of equity securities. However, assuming our drug candidates continue advancing, we will require significant additional resources and capital at some time after September 1, 2013 for our Phase 3 bremelanotide clinical trial program and other clinical trial programs. If our stockholders have not voted to increase the authorized number of shares of our common stock by September 1, 2013, we may not be able to raise additional funds through either equity or debt financings, may be required to curtail operations significantly, cease clinical trials and further decrease staffing levels and may not be to able continue operating as a going concern.

Under agreements relating to our 2012 private placement, we are required to allow purchasers in the 2012 private placement to participate in certain future equity and debt financings, which may restrict our ability to raise funds on acceptable terms, or at all.

For six years after our 2012 private placement, unless the purchasers own less than 20% of our outstanding common stock calculated as if the warrants were exercised, the purchasers have the right of first negotiation on any subsequent equity or debt financing. If we do not agree to terms of a financing with them, and negotiate with a third party on a financing, we must offer to sell to the purchasers at least 55% of the financing, and the purchasers may elect to purchase all or a portion of the financing. Assuming our drug candidates continue advancing, we will require significant additional resources and capital at some time for our Phase 3 bremelanotide clinical trial program and other clinical trial programs. The right of first negotiation and right of participation granted to the purchasers in our 2012 private placement may make it more difficult to raise additional funding through public or private equity financings, debt financings or other sources. Such funding may not be available on acceptable terms, or at all.

Under agreements relating to our 2012 private placement, so long as any Series A 2012 or Series B 2012 warrants are outstanding, we are required to oppose any takeover or change of control that does not provide specified rights to holders of Series A 2012 and Series B 2012 warrants.

Under the purchase agreement and form of warrants for our 2012 private placement, so long as any warrants remain outstanding we are required to (i) not permit, (ii) take necessary action to prevent both the occurrence or consummation of, and (iii) not be a party to any fundamental transaction, change of control or similar event unless contractually-specified rights are provided with respect to payment of a warrant early termination price tied to the greater of the then market price of our common stock or the amount per share paid to any other person. We are also required, subject to the exercise by our board of its fiduciary duties, to take all reasonable efforts to adopt a poison pill or any other anti-takeover provision or method necessary to prevent the fundamental transaction, change of control or similar event. The application of the provisions could have the effect of delaying or preventing a change of control or other fundamental transaction, which could adversely affect the market price of our common stock, and could make any potential acquisition of similar change of control more costly.

If we fail to obtain stockholder approval to increase the authorized number of shares of our common stock by specified dates, we will be required to pay interest on the value of the shares of common stock underlying the Series B

2012 warrants that cannot be issued.

In the event that we do not increase the authorized number of shares of our common stock on or prior to September 30, 2012, then until either the authorized number of shares of common stock is increased or such time as no Series B 2012 warrants remain outstanding, we are contractually obligated to pay interest semi-annually on the value of the Series B 2012 warrants at 10% per year. The value of the Series B 2012 warrants is the greater of $0.50 per share underlying the Series B 2012 warrants and the average of the dollar volume-weighted average price of our common stock for each trading day in the six month period during which interest is payable. There are Series B 2012 warrants to purchase up to 35,488,380 shares of our common stock currently outstanding. Based upon the $0.50 minimum value per share for purposes of calculating interest, the minimum annual interest payment would be $1,774,419. There is no maximum value per share for purposes of calculating interest. If we are required to pay interest, this will reduce the amount of our capital available for development of our product candidates, and will result in expenditures that provide no economic benefit to our stockholders other than holders of Series B 2012 warrants. We have called a special meeting of stockholders for September 27, 2012 to vote on increasing the authorized number of shares of our common stock. If the stockholders approve the increase, then no interest will be payable on the Series B 2012 warrants. However, there can be no assurance that the stockholders will approve the increase at the special meeting on September 27, 2012 or ever.

If we fail to obtain stockholder approval to increase the authorized number of shares of our common stock by specified dates, we may be required to redeem the Series B 2012 warrants, which redemption is at a price related to the then current average price of our common stock.

If we have not increased the authorized number of shares of our common stock on or prior to September 30, 2012, then at any time the holders of the Series B 2012 warrants may deliver a "Put Notice" to us. This Put Notice requires that we, on June 30, 2013 or within five days of any later date when a Put Notice is delivered, redeem all or a part of any Series B 2012 warrant. To redeem, we must pay the holder an amount equal to the number of shares underlying the Series B 2012 warrant to be redeemed multiplied by the average of the highest ten consecutive day dollar volume-weighted average price of our common stock at any time after July 3, 2012 and until the later of June 30, 2013 or the date the Put Notice is delivered to us. The following table illustrates the redemption price payable, if the holders of Series B 2012 warrants have delivered a Put Notice as to all Series B 2012 warrants, and if the stockholders have not increased the authorized number of shares of common stock by June 30, 2013.

| Redemption Price of All Series B 2012 Warrants (35,488,380 Shares) | |
|---|---|
| Highest 10-Day Price of Common Stock | Redemption Price |
| $0.50 | $17,744,190 |
| $0.75 | $26,616,285 |
| $1.00 | $35,488,380 |
| $2.00 | $70,976,760 |

The holder of a Series B 2012 warrant can deliver a Put Notice as to any portion of that Series B 2012 warrant. Thus, a holder could deliver a Put Notice as to a portion of its Series B 2012 warrant and, after June 30, 2013, compel redemption as to the specified portion, and could continue to hold the remaining portion of the Series B 2012 warrant. The portion of the Series B 2012 warrant which is not redeemed pursuant to the Put Notice will continue accruing interest, and the holder can thereafter, at any time, deliver a Put Notice as to the remaining portion of the Series B 2012 warrant. At any time after a Put Notice is delivered and until the redemption price is paid, the holder may withdraw a Put Notice and may thereafter deliver another Put Notice. If the ten consecutive day dollar volume-weighted price of our common stock increases prior to delivering a subsequent Put Notice, then that higher price will be used to calculate the price to redeem the Series B 2012 warrant shares. The redemption price is a function solely of the ten consecutive day dollar volume-weighted price of our common stock, and there is no upper limit on the redemption price. We may not have sufficient funds to pay redemption prices when due, and in that event will not be able to continue operating as a going concern. If we have sufficient funds to pay the redemption prices, this will reduce the amount of our capital available for development of our product candidates, and will result in expenditures that provide no economic benefit to our stockholders other than holders of Series B 2012 warrants. We have called a special meeting of stockholders for September 27, 2012 to vote on increasing the authorized number of shares of our common stock. If the stockholders approve the increase, then the Series B 2012 warrants will no longer be subject to redemption at the option of the holder. However, there can be no assurance that the stockholders will approve the increase at the special meeting on September 27, 2012 or ever.

Until our stockholders increase the number of authorized shares of our common stock, under Financial Accounting Standards Board Accounting Standards Codification Topic 815, "Derivatives and Hedging," the portion of the Series B 2012 warrants above the then authorized level of our common stock will be required to be classified as a liability and carried at their current fair value on our balance sheet and financial statements.

Until our stockholders increase the number of authorized shares of our common stock, under Financial Accounting Standards Board Accounting Standards Codification Topic 815, "Derivatives and Hedging," the portion of the Series B

2012 warrants above the then authorized level of our common stock will be required to be classified as a liability and carried at their current fair value on our balance sheet. We will be required to calculate the then current fair value of the Series B 2012 warrants each quarter, and classify this amount as a liability, with the change in fair value recorded as income or expense in our statement of operations. The fair value will be calculated by multiplying the number of shares underlying the Series B 2012 warrants above the then authorized level of our common stock by the closing price of our common stock on the last day in the relevant quarter or other period less the exercise price of $0.01 per share. When the stockholders increase the number of authorized shares of our common stock, the Series B 2012 warrants will cease to be classified as a liability, and the then fair value of the warrant liability will be reclassified into stockholders' equity. The following table shows the aggregate fair value as of July 3, 2012 (the closing date of the private placement offering) and hypothetically for June 30, 2013. This table assumes that all Series B 2012 warrants are above the then authorized level of our common stock, and assumes, solely for purposes of illustration, that the closing common stock price per share at June 30, 2013 is $1.00. The $1.00 closing price per share at June 30, 2013 is only an example, and the actual common stock price per share may be materially different.

| | July 3, 2012 | June 30, 2013 |
|---|---|---|
| Aggregate fair value | $ 17,034,422 | $ 35,133,496 |
| Exercise price | $ 0.01 | $ 0.01 |
| Common stock price (per share) | $ 0.49 | $ 1.00 |

As can be seen from this table, and assuming that the closing price of our common stock at June 30, 2013 is $1.00, we would be required to carry the aggregate fair value of $35,133,496 as a liability on our balance sheet. That amount will directly decrease our stockholders' equity, and based on our projections, will cause our stockholders' equity to fall below $6,000,000. If our stockholders' equity falls below $6,000,000 in any quarter, we will no longer be in compliance with continued listing standards of the principal exchange on which our common stock trades, NYSE MKT (formerly NYSE Amex). If we are not in compliance with continued listing standards, our common stock may be delisted from NYSE MKT. If we are delisted, then our common stock will trade, if at all, only on the over-the-counter market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. Delisting of our common stock from NYSE MKT could also further depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from NYSE MKT could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities.

We have called a special meeting of stockholders for September 27, 2012 to vote on increasing the authorized number of shares of our common stock. If the stockholders approve the increase, then the Series B 2012 warrants will no longer be classified as a liability, and the then fair value of the warrant liability will be reclassified into stockholders' equity. However, there can be no assurance that the stockholders will approve the increase at the special meeting on September 27, 2012 or ever.

Risks Relating to Owning Our Common Stock

As of September 7, 2012, there were 59,892,435 shares of common stock underlying outstanding convertible preferred stock, options, restricted stock units and warrants (excluding 35,488,380 shares underlying Series B 2012 warrants – see the paragraph below the bullet list). Stockholders may experience dilution from the conversion of preferred stock, exercise of outstanding options and warrants and vesting of restricted stock units.

As of September 7, 2012, holders of our outstanding dilutive securities had the right to acquire the following amounts of underlying common stock:

- 52,834 shares issuable on the conversion of immediately convertible Series A Convertible preferred stock, subject to adjustment, for no further consideration;

- 2,758,633 shares issuable on the exercise of stock options, at exercise prices ranging from $0.65 to $42.10 per share;

- 472,500 shares issuable under restricted stock units which vest on dates between June 22, 2013 and July 17, 2014, subject to the fulfillment of service conditions; and

- 56,608,468 shares issuable on the exercise of warrants at exercise prices ranging from $0.01 to $4.12 per share.

In addition to the securities listed above, in the private placement which closed July 3, 2012 we issued Series B 2012 warrants to purchase up to 35,488,380 shares of common stock at $0.01 per share. These warrants will not be exercisable unless and until we increase our authorized capital (the maximum number of shares of common stock that

we can issue). We have called a special meeting of stockholders for September 27, 2012 to vote on approving an increase. If the stockholders approve the increase, then the Series B 2012 warrants will become exercisable. In that case, a total of 95,380,815 shares will be issuable on conversion, exercise or vesting of these dilutive securities.

If the holders convert, exercise or receive these securities, or similar dilutive securities we may issue in the future, stockholders may experience dilution in the net tangible book value of their common stock. In addition, the sale or availability for sale of the underlying shares in the marketplace could depress our stock price. We have registered or agreed to register for resale substantially all of the underlying shares listed above. Holders of registered underlying shares could resell the shares immediately upon issuance, which could result in significant downward pressure on our stock price.

Our stock price is volatile and we expect it to remain volatile, which could limit investors' ability to sell stock at a profit.

The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

- publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- delay or failure in initiating, completing or analyzing preclinical or clinical trials or unsatisfactory designs or results of these trials;
- interim decisions by regulatory agencies, including the FDA, as to clinical trial designs, acceptable safety profiles and the benefit/risk ratio of products under development;
- achievement or rejection of regulatory approvals by our competitors or by us;
- announcements of technological innovations or new commercial products by our competitors or by us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- regulatory developments in the United States and foreign countries;
- whether our stockholders approve an increase in our authorized common stock, such that we avoid interest payments and certain other contractual obligations relating to our Series B 2012 warrants;
- economic or other crises and other external factors;
- period-to-period fluctuations in our revenue and other results of operations;
- changes in financial estimates by securities analysts; and
- sales of our common stock.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance. If our revenues, if any, in any particular period do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our operating results to suffer further. If our operating results in any future period fall below the expectations of securities analysts or investors, our stock price may fall by a significant amount.

For the 12 month period ended August 31, 2012, the price of our stock has been volatile, ranging from a high of $1.20 per share to a low of $0.39 per share.

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

We do not intend to pay cash dividends in the foreseeable future.

We do not anticipate paying any cash dividends in the foreseeable future and intend to retain future earnings, if any, for the development and expansion of our business. In addition, the terms of existing or future agreements may limit our ability to pay dividends. Therefore, our stockholders will not receive a return on their shares unless the value of their shares increases.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our corporate offices are located at 4B Cedar Brook Drive, Cedar Brook Corporate Center, Cranbury, NJ 08512, where we lease approximately 10,000 square feet of office space under a lease that expires in 2015. The leased property is in good condition.

Item 3. Legal Proceedings.

We are involved, from time to time, in various claims and legal proceedings arising in the ordinary course of our business. We are not currently a party to any such claims or proceedings that, if decided adversely to us, would either individually or in the aggregate have a material adverse effect on our business, financial condition or results of operations.

Item 4. Mine Safety Disclosures.

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

The table below provides, for the fiscal quarters indicated, the reported high and low sales prices for our common stock on the NYSE MKT (formerly NYSE Amex) since July 1, 2010. Prices per share of our common stock have been adjusted for the one-for-ten reverse stock split on September 27, 2010 on a retroactive basis.

| FISCAL YEAR ENDED JUNE 30, 2012 | HIGH | LOW |
|---|---|---|
| Fourth Quarter | $ 0.77 | $ 0.40 |
| Third Quarter | 0.75 | 0.39 |
| Second Quarter | 0.73 | 0.39 |
| First Quarter | 1.28 | 0.50 |

| FISCAL YEAR ENDED JUNE 30, 2011 | HIGH | LOW |
|---|---|---|
| Fourth Quarter | $ 1.38 | $ 0.79 |
| Third Quarter | 1.45 | 0.78 |
| Second Quarter | 1.90 | 0.84 |
| First Quarter | 2.40 | 1.26 |

Our common stock has been listed on NYSE MKT under the symbol "PTN" since December 21, 1999. It previously traded on The Nasdaq SmallCap Market under the symbol "PLTN."

Holders of common stock. On September 7, 2012, we had approximately 225 record holders of common stock and the closing sales price of our common stock as reported on the NYSE MKT was $0.64 per share.

Dividends and dividend policy. We have never declared or paid any dividends. We currently intend to retain earnings, if any, for use in our business. We do not anticipate paying dividends in the foreseeable future.

Dividend restrictions. Our outstanding Series A Preferred Stock, consisting of 4,697 shares on September 7, 2012, provides that we may not pay a dividend or make any distribution to holders of any class of stock unless we first pay a special dividend or distribution of $100 per share to the holders of the Series A Preferred Stock.

So long as the purchasers in our 2012 private placement own at least 20% of our outstanding common stock, calculated as if any warrants held by the purchasers were exercised, we may not declare or pay any dividend or make any distribution to holders of any class of stock or stock rights.

Equity Compensation Plan Information. Reference is made to the information contained in the Equity Compensation Plan table contained in Item 12 of this Annual Report.

Item 6. Selected Financial Data.

Not applicable.

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

The following discussion and analysis should be read in conjunction with the consolidated financial statements and notes to the consolidated financial statements filed as part of this Annual Report.

Critical Accounting Policies.

Our significant accounting policies are described in Note 2 to the consolidated financial statements included in this Annual Report. We believe that our accounting policies and estimates relating to revenue recognition, accrued expenses and stock-based compensation charges are the most critical.

Revenue Recognition

Revenue from corporate collaborations and licensing agreements consists of up-front fees, research and development funding and milestone payments. Non-refundable up-front fees are deferred and amortized to revenue on a straight-line basis over the related performance period. We estimate the performance period as the period in which we perform certain development activities under the applicable agreement. Reimbursements for research and development activities are recorded in the period that we perform the related activities under the terms of the applicable agreements. Revenue resulting from the achievement of milestone events stipulated in the applicable agreements is recognized when the milestone is achieved, provided that such milestone is substantive in nature. Revenue from grants is recognized as we provide the services stipulated in the underlying grants based on the time and materials incurred.

The $10.0 million upfront payment received in January 2007 under the AstraZeneca agreement and the additional $5.0 million received pursuant to the September 2009 amendment have been recognized as revenue over the period ended January 2010, the completion of the research collaboration portion of the licensing and research collaboration agreement.

Accrued Expenses

Third parties perform a significant portion of our development activities. We review the activities performed under significant contracts each quarter and accrue expenses and the amount of any reimbursement to be received from our collaborators based upon the estimated amount of work completed. Estimating the value or stage of completion of certain services requires judgment based on available information. If we do not identify services performed for us but not billed by the service-provider, or if we underestimate or overestimate the value of services performed as of a given date, reported expenses will be understated or overstated.

Stock-based Compensation

The fair value of stock options granted has been calculated using the Black-Scholes option pricing model, which requires us to make estimates of expected volatility and expected option lives. We estimate these factors at the time of grant based on our own prior experience, public sources of information and information for comparable companies. The amount of recorded compensation related to an option grant is not adjusted for subsequent changes in these estimates or for actual experience. The amount of our recorded compensation is also dependent on our estimates of future option forfeitures and the probability of achievement of performance conditions. If we initially over-estimate future forfeitures, our reported expenses will be understated until such time as we adjust our estimate. Changes in estimated forfeitures will affect our reported expenses in the period of change and future periods.

The amount and timing of compensation expense to be recorded in future periods related to grants of restricted stock units may be affected by employment terminations. As a result, stock-based compensation charges may vary significantly from period to period.

Results of Operations

Year Ended June 30, 2012 Compared to the Year Ended June 30, 2011:

Revenue – For the fiscal year ended June 30, 2012 (fiscal 2012), we recognized $0.1 million in revenue, compared to $1.5 million for the fiscal year ended June 30, 2011 (fiscal 2011). Revenue from AstraZeneca for fiscal 2012 and fiscal 2011 consisted of $0.1 million and $0.5 million, respectively, of reimbursement of development costs and per-employee compensation, earned at the contractual rate. Fiscal 2011 revenue also included $1.0 million of federal grants under the Patient Protection and Affordable Care Act of 2010.

Research and Development – Research and development expenses increased to $13.8 million for fiscal 2012 compared to $10.4 million for fiscal 2011. This increase is primarily the result of costs relating to our on-going Phase 2B clinical trial evaluating the efficacy and safety of bremelanotide for the treatment of FSD, which commenced in June 2011.

Research and development expenses related to our bremelanotide, PL-3994, peptide melanocortin agonists, obesity, NeutroSpec and other preclinical programs were $9.9 million and $3.9 million in fiscal years 2012 and 2011, respectively. Spending to date has been primarily related to our Phase 2B clinical trial evaluating the efficacy and safety of bremelanotide for the treatment of FSD. The amount of such spending and the nature of future development activities are dependent on a number of factors, including primarily the availability of funds to support future development activities, success of our clinical trials and preclinical and discovery programs, and our ability to

progress compounds in addition to bremelanotide and PL-3994 into human clinical trials.

The amounts of project spending above exclude general research and development spending, which decreased to $3.9 million for fiscal 2012 compared to $6.5 million for fiscal 2011. This decrease is the result of reducing staffing levels pursuant to our strategic decision announced in September 2010 to focus resources and efforts on clinical trials of bremelanotide and PL-3994 and preclinical development of an inhaled formula of PL-3994 and a new peptide drug candidate for sexual dysfunction.

Cumulative spending from inception to June 30, 2012 on our bremelanotide, NeutroSpec (a previously marketed imaging product on which all work is suspended) and other programs (which includes PL-3994, other peptide melanocortin agonists, obesity and other discovery programs) amounts to approximately $154.7 million, $55.6 million and $59.4 million, respectively. Due to various risk factors described in this Annual Report, including the difficulty in currently estimating the costs and timing of future Phase 1 clinical trials and larger-scale Phase 2 and Phase 3 clinical trials for any product under development, we cannot predict with reasonable certainty when, if ever, a program will advance to the next stage of development or be successfully completed, or when, if ever, related net cash inflows will be generated. See Item 1A - Risk Factors.

General and Administrative – General and administrative expenses increased to $5.0 million for fiscal 2012 compared to $4.8 million for fiscal 2011. This increase is primarily the result of increases in stock-based compensation and professional fees.

Income Tax Benefit – Income tax benefits of $1.1 million in fiscal 2012 and $0.6 million in fiscal 2011 relate to the sale of New Jersey state net operating loss carryforwards. The amount of such losses and tax credits that we are able to sell depends on annual pools and allocations established by the state of New Jersey.

Year Ended June 30, 2011 Compared to the Year Ended June 30, 2010:

Revenue – For fiscal 2011, we recognized $1.5 million in revenue, which includes $1.0 million of federal grants under the Patient Protection and Affordable Care Act of 2010, compared to $14.2 million for the fiscal year ended June 30, 2010 (fiscal 2010).

Revenue from AstraZeneca for fiscal 2011 consisted of $0.5 million of reimbursement of development costs and per-employee compensation, earned at the contractual rate. Revenue from AstraZeneca for fiscal 2010 consisted of $3.2 million related to our research services performed, and $11.0 million related to AstraZeneca’s up-front license fee. In connection with the completion of the research collaboration portion of the licensing and research collaboration agreement, we recognized as revenue in fiscal 2010 all remaining deferred up-front license fees received from AstraZeneca.

Research and Development – Research and development expenses decreased to $10.4 million for fiscal 2011 compared to $12.3 million for fiscal 2010. The decrease is the result of reducing staffing levels pursuant to our strategic decision announced in September 2010 to focus resources and efforts on clinical trials of bremelanotide and PL-3994 and preclinical development of an inhaled formula of PL-3994 and a new peptide drug candidate for sexual dysfunction.

Research and development expenses related to our bremelanotide, PL-3994, peptide melanocortin agonists, obesity, NeutroSpec and other preclinical programs were $3.9 million and $4.1 million in fiscal years 2011 and 2010, respectively. Spending to date has been primarily related to our Phase 2B clinical trial evaluating the efficacy and safety of bremelanotide for the treatment of FSD and secondarily to the identification and optimization of lead compounds and to study the effects of melanocortin receptor-specific compounds on food intake, obesity and other metabolic parameters and preclinical studies and a Phase 1 trial with subcutaneously administered bremelanotide. The amount of such spending and the nature of future development activities are dependent on a number of factors, including primarily the availability of funds to support future development activities, success of our clinical trials and preclinical and discovery programs, and our ability to progress compounds in addition to bremelanotide and PL-3994 into human clinical trials.

The historical amounts of project spending above exclude general research and development spending, which decreased to $6.5 million for fiscal 2011 compared to $8.2 million for fiscal 2010. This decrease is the result of reducing staffing levels pursuant to our strategic decision announced in September 2010 to focus resources and efforts

on clinical trials of bremelanotide and PL-3994 and preclinical development of an inhaled formula of PL-3994 and a new peptide drug candidate for sexual dysfunction.

Cumulative spending from inception to June 30, 2011 on our bremelanotide, NeutroSpec (a previously marketed imaging product on which all work is suspended) and other programs (which includes PL-3994, other melanocortin receptor agonists, obesity and other discovery programs) amounts to approximately $141.4 million, $55.6 million and $58.9 million, respectively. Due to various risk factors described in this Annual Report, including the difficulty in currently estimating the costs and timing of future Phase 1 clinical trials and larger-scale Phase 2 and Phase 3 clinical trials for any product under development, we cannot predict with reasonable certainty when, if ever, a program will advance to the next stage of development or be successfully completed, or when, if ever, related net cash inflows will be generated. See Item 1A - Risk Factors.

General and Administrative – General and administrative expenses decreased to $4.8 million for fiscal 2011 compared to $4.9 million for fiscal 2010. The decrease is the result of reducing staffing levels pursuant to our strategic decision announced in September 2010 to focus resources and efforts on clinical trials of bremelanotide and PL-3994 and preclinical development of an inhaled formula of PL-3994 and a new peptide drug candidate for sexual dysfunction, offset by the granting of cash and equity bonuses to employees approved by our compensation committee in June 2011.

Income Tax Benefit – Income tax benefits of $0.6 million in fiscal 2011 and $1.0 million in fiscal 2010 relate to the sale of New Jersey state net operating loss carryforwards. The amount of such losses and tax credits that we are able to sell depends on annual pools and allocations established by the state of New Jersey.

Liquidity and Capital Resources

Since inception, we have incurred net operating losses, primarily related to spending on our research and development programs. We have financed our net operating losses primarily through equity financings and amounts received under collaborative agreements.

Our product candidates are at various stages of development and will require significant further research, development and testing and some may never be successfully developed or commercialized. We may experience uncertainties, delays, difficulties and expenses commonly experienced by early stage biopharmaceutical companies, which may include unanticipated problems and additional costs relating to:

- the development and testing of products in animals and humans;
- product approval or clearance;
- regulatory compliance;
- good manufacturing practices;
- intellectual property rights;
- product introduction;
- marketing, sales and competition; and
- obtaining sufficient capital.

Failure to enter into collaboration agreements and obtain timely regulatory approval for our product candidates and indications would impact our ability to increase revenues and could make it more difficult to attract investment capital for funding our operations. Any of these possibilities could materially and adversely affect our operations and require us to curtail or cease certain programs.

During fiscal 2012, we used $15.5 million of cash for our operating activities, compared to $11.0 million used in fiscal 2011 and $5.7 million used in fiscal 2010. Higher net cash outflows from operations in fiscal 2012 and 2011 resulted primarily from lower revenues and the increased costs relating to our on-going Phase 2B clinical trial evaluating the efficacy and safety of bremelanotide for the treatment of FSD. Net cash outflows from operations in fiscal 2010 were favorably impacted by the decrease in research and development expenses and the receipt of $5.0 million in additional payments from AstraZeneca. Our periodic accounts receivable balances will continue to be highly dependent on the

timing of receipts from collaboration partners and the division of development responsibilities between us and our collaboration partners.

During fiscal 2012, cash provided by investing activities consisted mainly of $0.5 million from the sale of supplies and equipment. During fiscal 2011, cash provided by investing activities was $3.4 million from the sale of available-for-sale investments. During fiscal 2010, cash provided by investing activities consisted mainly of $45,000 from the sale of supplies and equipment.

During fiscal 2012, net cash used in financing activities was $35,000, consisting entirely of payments on capital lease obligations. During fiscal 2011, cash provided by financing activities was approximately $21.0 million, primarily from net proceeds pursuant to the completion of our firm commitment public offering that closed on March 1, 2011 offset by payments on capital lease obligations of $23,000 and payment of withholding taxes related to restricted stock units of $26,000. The offering consisted of the sale of 23,000,000 units at a price to the public of $1.00 per unit. The units consisted of 23,000,000 shares of our common stock, Series A 2011 warrants to purchase up to 2,000,000 shares of our common stock, and Series B 2011 warrants to purchase up to 21,000,000 shares of our common stock. During fiscal 2010, net cash provided by financing activities was $6.7 million, primarily reflecting the aggregate net proceeds of approximately $7.0 million from the sales in August 2009, February 2010 and June 2010 of 948,485 units, 962,963 units and 1,000,000 units, respectively, in registered direct offerings. Each unit from the August 2009 offering consisted of one share of common stock and a five-year warrant to purchase 0.35 shares of common stock. Each unit from the February 2010 offering consisted of one share of common stock, a Series A warrant exercisable for 0.33 shares of our common stock and a Series B warrant exercisable for 0.33 shares of common stock.

We have incurred cumulative negative cash flows from operations since our inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. As of June 30, 2012, our cash and cash equivalents were $3.8 million and our current liabilities were $3.5 million. In addition, on July 3, 2012, we closed on a $35.0 million private placement. The offering consisted of the sale of 3,873,000 shares of our common stock, Series A 2012 warrants to purchase up to 31,988,151 shares of our common stock and Series B 2012 warrants to purchase up to 35,488,380 shares of our common stock. Funds under the management of QVT Financial LP paid $0.50 for each share of common stock and $0.49 for each Series A 2012 warrant and each Series B 2012 warrant, with the warrants exercisable at $0.01 per share. The net proceeds to us after deducting the offering expenses were $34.5 million (See Note 12 to the consolidated financial statements included in this Annual Report).

We have certain contractual obligations, including an obligation to pay interest on Series B 2012 warrants and to redeem Series B 2012 warrants, in the event that the number of our authorized shares of common stock is not increased by specified dates. If the authorized number of shares of common stock is not increased by September 30, 2012, we are required to commence paying 10% per year interest on the fair value of shares underlying the Series B 2012 warrants, with a minimum value determination of $0.50 per share, which would result in a minimum annual interest payment of $1.8 million. If the authorized number of shares of common stock is not increased by June 30, 2013, the holders of Series B 2012 warrants can compel redemption of all or a portion of Series B 2012 warrants at the average of the highest ten consecutive day dollar volume-weighted price average price of our common stock. The redemption amount payable is a function solely of the ten consecutive day dollar volume-weighted price of our common stock, and there is no upper limit on the redemption price. We may not have sufficient funds to pay redemption prices when due, and in that event will not be able to continue operating as a going concern. If we have sufficient funds to pay the redemption prices, this will reduce the amount of our capital available for development of our product candidates, and will result in expenditures that provide no economic benefit to our stockholders other than holders of Series B 2012 warrants. We have called a special meeting of stockholders for September 27, 2012 to vote on increasing the authorized number of shares of our common stock. If the stockholders approve the increase, then no interest will be payable on the Series B 2012 warrants, and the Series B 2012 warrants will no longer be subject to redemption. However, there can be no assurance that the stockholders will approve the increase at the special meeting on September 27, 2012 or ever.

Assuming stockholder approval of the increase in authorized common stock, we believe that our cash and cash equivalents as of June 30, 2012, together with the net proceeds from private placement with net proceeds of $34.5 million, are adequate to fund our planned operations, including completion of our Phase 2B clinical trial with bremelanotide for FSD, through at least calendar year 2013. Over the next twelve months we intend to focus efforts on preparing for our Phase 3 clinical trial with bremelanotide for FSD, assuming that results of the Phase 2B trial support advancing the program, conducting preclinical research on one or more peptide melanocortin agonists for sexual dysfunction and other indications, conducting preclinical research on peptide melanocortin agonists for inflammatory disease related indications, and development and testing of an inhaled formulation of PL-3994. If stockholders do not approve the increase in authorized common stock by September 30, 2012, we are contractually obligated to pay interest semi-annually on the value of the Series B 2012 warrants at 10% per year, with minimum annual interest payments of $1.8 million, and a maximum depending on the average dollar volume-weighted price of our common stock. If stockholders do not approve the increase in authorized common stock by June 30, 2013, holders of Series B 2012 warrants can require redemption of all or a part of those warrants at a price determined by the ten consecutive day dollar volume-weighted price of our common stock. We cannot predict the redemption price or the number of warrants, if any, which holders will seek to redeem, or whether we will have sufficient funds to pay redemption prices when and if due.

Our current cash and cash equivalents are not sufficient to complete all of the clinical trials required for product approval for any of our products. We expect that the Phase 3 bremelanotide clinical trial program for FSD, which will not commence before calendar year 2013, will require significant additional resources and capital. We intend to seek additional capital through public or private equity or debt financings, collaborative arrangements on our product

candidates, including bremelanotide for FSD, or other sources. However, sufficient additional funding to support operations past calendar year 2013, including Phase 3 clinical trials with bremelanotide, may not be available on acceptable terms or at all. If additional funding is not available, we will be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available, and relinquish, license or otherwise dispose of rights on unfavorable terms to technologies and product candidates that we would otherwise seek to develop or commercialize ourselves. The nature and timing of our development activities are highly dependent on our financing activities.

We anticipate incurring additional losses over at least the next few years. To achieve profitability, if ever, we, alone or with others, must successfully develop and commercialize our technologies and proposed products, conduct preclinical studies and clinical trials, obtain required regulatory approvals and successfully manufacture and market such technologies and proposed products. The time required to reach profitability is highly uncertain, and we do not know whether we will be able to achieve profitability on a sustained basis, if at all.

Off-Balance Sheet Arrangements

None.

Contractual Obligations

We have entered into various contractual obligations and commercial commitments. The following table summarizes our most significant contractual obligations as of June 30, 2012:

| | Payments due by Period | | | | |
|---|---|---|---|---|---|
| | Total | Less than 1 Year | 1 - 3 Years | 3 - 5 Years | More than 5 Years |
| Facility operating leases | $819,576 | $346,906 | $472,670 | $- | $- |
| Capital lease obligations | 45,353 | 24,738 | 20,615 | - | - |
| Total contractual obligations | $864,929 | $371,644 | $493,285 | $- | $- |

Our license agreement related to NeutroSpec require royalty payments on commercial net sales and payments of up to $2.25 million contingent on the achievement of specified cumulative net margins on sales by Mallinckrodt. No contingent amounts will be payable related to NeutroSpec unless we recommence sales and marketing of NeutroSpec. We do not expect to make any such contingent payments during the next twelve months.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

Table of Contents
Consolidated Financial Statements

The following consolidated financial statements are filed as part of this Annual Report:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Palatin Technologies, Inc.:

We have audited the accompanying consolidated