

PALATIN TECHNOLOGIES INC
Form 10-K
September 27, 2013

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

FORM 10 - K

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

For the fiscal year ended June 30, 2013

or

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

For the transition period from _____ to _____

Commission file number: 001-15543

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

Delaware
(State or other jurisdiction of incorporation
or organization)

95-4078884
(I.R.S. Employer Identification No.)

4B Cedar Brook Drive
Cranbury, New Jersey
(Address of principal executive offices)

08512
(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 ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the

Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

Act. Yes ☐ No ☒

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. ☐

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	<input type="radio"/>	Accelerated filer	<input type="radio"/>
Non-accelerated filer	<input type="radio"/>	Smaller reporting company	<input checked="" type="radio"/>
(Do not check if a smaller reporting company)			

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

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, 2012): \$23,096,569.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date (September 26, 2013): 39,191,655.

PALATIN TECHNOLOGIES, INC.

Table of Contents

	Page
<u>PART I</u>	
<u>Item 1. Business</u>	3
<u>Item</u>	
<u>1A. Risk Factors</u>	13
<u>Item</u>	
<u>1B. Unresolved Staff Comments</u>	23
<u>Item 2. Properties</u>	23
<u>Item 3. Legal Proceedings</u>	23
<u>Item 4. Mine Safety Disclosures</u>	23
<u>PART II</u>	
<u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases</u>	
<u>Item 5. of Equity Securities</u>	24
<u>Item 6. Selected Financial Data</u>	24
<u>Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	25
<u>Item</u>	
<u>7A. Quantitative and Qualitative Disclosures About Market Risk</u>	28
<u>Item 8. Financial Statements and Supplementary Data</u>	29
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	48
<u>Item</u>	
<u>9A. Controls and Procedures</u>	48
<u>Item</u>	
<u>9B. Other Information</u>	48
<u>PART III</u>	
<u>Item</u>	
<u>10. Directors, Executive Officers and Corporate Governance</u>	49
<u>Item</u>	
<u>11. Executive Compensation</u>	53
<u>Item Security Ownership of Certain Beneficial Owners and Management and Related</u>	
<u>12. Stockholder Matters</u>	59
<u>Item</u>	
<u>13. Certain Relationships and Related Transactions, and Director Independence</u>	64
<u>Item</u>	
<u>14. Principal Accountant Fees and Services</u>	64
<u>PART IV</u>	
<u>Item</u>	
<u>15. Exhibits, Financial Statement Schedules</u>	65

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,” the “Company” 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, dermatologic diseases and inflammatory diseases.

The following drug development programs are actively under development:

Bremelanotide, an on-demand subcutaneous injectable peptide melanocortin receptor agonist, for treatment of FSD. Bremelanotide is scheduled to start Phase 3 clinical trials in the first quarter of calendar 2014.

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.

Melanocortin receptor-1 agonist (MC1R) peptides, for treatment of dermatologic and inflammatory disease indications.

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

[Back to Table of Contents](#)

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). We have completed a Phase 2B clinical trial and end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA), and are planning to start pivotal Phase 3 clinical trials in the first quarter of calendar 2014.

Ongoing Clinical Trials and Clinical Plans. The Phase 2B clinical trial was a multicenter, 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 was to measure safety and efficacy of subcutaneous doses intended for on-demand, home use. The primary efficacy endpoint was change from baseline to end of study in the number of satisfying sexual events.

In the Phase 2B clinical trial, the primary endpoint data analysis of 327 pre-menopausal women with female sexual arousal disorder and/or hypoactive sexual desire disorder showed statistically significant increases in the number of satisfying sexual events, and statistically significant improvement in measures of overall sexual functioning and distress related to sexual dysfunction, for women taking bremelanotide compared to placebo. Bremelanotide was well-tolerated during the trial. The most common types of treatment-emergent adverse events reported more frequently in the bremelanotide arms were facial flushing, nausea and emesis, which were mainly mild-to-moderate in severity. Adverse events that most commonly led to discontinuation were nausea and emesis. No serious adverse events were attributable to bremelanotide during the trial.

In the end-of-Phase 2 meeting with the FDA on bremelanotide for FSD we reached preliminary agreement on key aspects of Phase 3 pivotal registration studies, including FSD patient population, primary and key secondary efficacy endpoints, general study design, dose selection and safety monitoring. In addition, the FDA agreed that the Phase 2 data adequately characterized blood pressure and heart rate signals of bremelanotide, and that standardized methods

for in-clinic assessment of blood pressure would be sufficient for Phase 3. Based upon the discussions with the FDA, we have completed protocols for the pivotal Phase 3 studies and are manufacturing drug product for clinical trial use and entering into agreements with clinical research organizations and others for Phase 3 studies.

The Phase 3 clinical study program will be conducted in premenopausal women with hypoactive sexual desire disorder, either with or without arousal difficulties, and will include two pivotal placebo-controlled, randomized parallel group trials each in 600 evaluable patients with two arms, one a fixed bremelanotide dose and one placebo. Hypoactive sexual desire disorder is the single largest specific diagnosis in FSD. We will also conduct open-label safety extension, drug interaction and other ancillary studies. The Phase 3 studies, which will be conducted in North America, will utilize a single-dose autoinjector intended for commercialization. It is anticipated that the Phase 3 program will take at least fifteen to eighteen months from initiation of patient dosing through database lock. Following database lock, clinical trial data will be analyzed and, assuming the data supports approval of bremelanotide for FSD, a New Drug Application (NDA) will be submitted to FDA. There can be no assurance that the Phase 3 data will support approval of bremelanotide for FSD or that the FDA will approve an NDA for bremelanotide.

[Back to Table of Contents](#)

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. Hypoactive sexual desire disorder, either with or without arousal difficulties, is the largest single category of FSD. To establish a diagnosis of FSD, these syndromes must be associated with personal distress, as determined by the affected women. The 2006 PRESIDE study, a cross-sectional, population-based survey of 31,581 female adult respondents in the United States, found that approximately 43% of women have symptoms associated with FSD, with up to about 22% having associated personal distress.

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

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 selected a simple and patient-friendly single dose, disposable auto-injector device which will be used in Phase 3 clinical trials and is intended for commercialization.

Prior Clinical Trials with Subcutaneous Administration. We have completed several Phase 1 clinical studies in which various safety parameters, including blood pressure effects of subcutaneously administered bremelanotide, were studied. Based in part on these studies, our Phase 2B clinical trial assessed the magnitude and duration of blood pressure effect, and determined that subcutaneous administration of selected doses of bremelanotide for treatment of FSD in premenopausal women provides acceptable control of blood pressure effects.

Clinical Trials with Intranasal Formulations. 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, over 2,500 subjects in 31 completed clinical studies received at least one dose of bremelanotide, with over 1,500 receiving multiple doses.

Next Generation Melanocortin Receptor-4 (MC4R) Peptide Agonists. We have developed a series of next generation highly selective MC4R peptides. 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 conditions responsive to MC4R, including FSD and ED. We are engaged in preclinical activities with these peptides, and are evaluating potential pharmaceutical applications.

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 initiated human clinical studies with AZD2820, a subcutaneously-administered peptide melanocortin receptor partial agonist that was being developed as a single-agent therapy for the treatment of obesity, but discontinued development 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 is evaluating its program and next steps. No assurance can be given that AstraZeneca will continue to develop compounds that target melanocortin receptors for the treatment of obesity, diabetes and related metabolic syndrome, or that AstraZeneca will be successful in developing any such compound.

[Back to Table of Contents](#)

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.

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.

Melanocortin Receptor-1 (MC1R) Peptide Agonists. We have initiated preclinical studies with MC1R peptide drug candidates for a number of indications, primarily dermatologic and inflammatory disease related. The MC1R is implicated in a number of diseases, including inflammatory indications such as inflammatory bowel disease and nephritis, dermatologic indications such as vitiligo and erythropoietic protoporphyria, and ocular indications such as uveitis and dry eye. We are conducting animal studies for a number of different indications, and if these efforts are successful, intend to select one or more clinical development candidates and indications during the current fiscal year. We will then start preclinical toxicology and other studies preparatory to filing an Investigational New Drug (IND) application with FDA.

Other Melanocortin Programs. We are continuing drug discovery efforts in the melanocortin field, primarily developing peptide compounds, including highly selective MC1R agonists and peptides specific for MC4R, including both agonists and antagonists.

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.

[Back to Table of Contents](#)

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 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 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.

[Back to Table of Contents](#)

Later in 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.

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 \$10.5 million for the fiscal year ended June 30, 2013 (fiscal 2013) and \$13.8 million for the fiscal year ended June 30, 2012 (fiscal 2012), of which \$0.01 and \$0.1 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.

[Back to Table of Contents](#)

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 not aware of any drug in clinical trials for FSD which is on-demand, taken in conjunction with anticipated sexual activity. We are aware of several drugs at various stages of development which are taken on a chronic, typically once-daily, basis. Flibanserin, a non-hormone oral drug, has been 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 has announced it has resubmitted an NDA to the FDA and expects FDA action before the end of 2013. An oral fixed-dose combination of two antidepressants, bupropion and trazodone, is reported to be entering Phase 2 studies in premenopausal women with hypoactive sexual desire disorder. Another company is developing two different oral fixed-dose combination drugs, one a combination of sildenafil and testosterone and the other a combination of testosterone and buspirone hydrochloride, and is conducting Phase 2 studies in premenopausal women with hypoactive sexual desire disorder. A drug utilizing a testosterone transdermal patch completed two Phase 3 efficacy trials for treatment of FSD in surgically post-menopausal women, but did not show statistical separation from placebo in those trials. It is not known whether this drug is still in development. 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 either a melanocortin receptor agonist drug for FSD or an on-demand drug for FSD.

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 we are not aware of any active development in the United States. We are aware of other companies developing intravenously administered natriuretic peptide drugs, with at least one reported to have completed 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.

[Back to Table of Contents](#)

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, New Zealand, 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 own an issued patent in the United States and New Zealand claiming an alternative class of melanocortin receptor-specific peptides for treatment of sexual dysfunction and patent applications on the same class 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. The presumptive term of the patent issued in the United States is 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, New Zealand 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 a narrow class of highly selective MC1R agonist peptides for treatment of inflammation-related diseases and disorders and related indications, and patent applications on two broader classes of highly selective MC1R agonist peptides 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. The presumptive term of the patent issued in the United States is 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. Corresponding patents have issued in the European patent office, South Africa, Russia, France, Germany, Mexico, Philippines and Colombia, and applications claiming the PL-3994 substance and other compounds, including precursor molecules, are pending in Australia, Brazil, Canada, China, India, Israel, Japan and Korea. We do not know the full scope of patent coverage we will obtain, or whether any patents will issue other than the patents already issued. 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.

[Back to Table of Contents](#)

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.

[Back to Table of Contents](#)

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 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 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 depends 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.

Payors frequently employ a tiered system in reimbursing end users for pharmaceutical products, with tier designation affecting copay or deductible amounts. 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 bremelanotide will be classified as a Tier 3 drug, so that 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 may adversely affect the market acceptance of bremelanotide. Further, healthcare reimbursement systems vary from country to country, and third-party reimbursement might not be made available for bremelanotide for FSD 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. We are in the process of negotiating 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 selected a delivery device, and are negotiating a long-term supply and manufacturing agreement, but may not be able to enter into such an agreement on acceptable terms, if at all.

[Back to Table of Contents](#)

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 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 \$10 million coverage in the aggregate as to certain clinical trial risks.

Employees

As of September 26, 2013, we employed 20 persons full time, of whom 13 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, 2013, we had an accumulated deficit of \$260.1 million. We expect to incur additional losses as we continue our development ofbremelanotide, 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

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, including funds required to complete our Phase 3 clinical trials of bremelanotide for FSD, and funds may not be available on acceptable terms, or at all.

As of June 30, 2013, we had cash, cash equivalents and short-term investments of \$24.4 million, with current liabilities of \$2.1 million. We believe we have sufficient currently available working capital to fund our currently planned operations through at least calendar year 2014, but our currently available working capital is not sufficient to complete pivotal Phase 3 clinical trials for bremelanotide for FSD. We will need additional funding to complete required clinical trials of bremelanotide for FSD and our other product candidates 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.

[Back to Table of Contents](#)

While we are actively preparing to initiate Phase 3 clinical trials of bremelanotide for FSD, we do not intend to start patient enrollment and dosing in the Phase 3 program unless we have adequate funds, or commitments for adequate funds, to complete the Phase 3 program. We estimate that the Phase 3 program, through submission of an NDA, will cost at least \$78.0 million. We are seeking funds to support the Phase 3 program through collaborative arrangements on bremelanotide, including marketing and distribution partnering agreements, public or private equity or debt financings, and other sources, but such additional funding may not be available on acceptable terms, or at all.

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 decrease staffing levels. We may seek to license, sell or otherwise dispose of our product candidates, technologies and contractual rights 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. Our Phase 2B clinical trial for FSD demonstrated what we believe is an acceptable safety profile and, at selected doses, statistically significant efficacy. However, results obtained in Phase 3 clinical trials may be inconsistent with results obtained in our Phase 2B study, and may demonstrate either an unacceptable safety profile or insufficient efficacy. It is also possible that safety or efficacy results obtained in Phase 3 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.

[Back to Table of Contents](#)

Even if bremelanotide for FSD obtains regulatory approval in the United States and other countries, it may not achieve significant market acceptance.

Regulatory approval for the marketing and sale of bremelanotide for FSD in the United States and other countries does not assure that the product will be a commercial success. While we believe that an on-demand drug for FSD has competitive advantages compared to chronic or daily use hormones and other drugs, we may not be able to realize this perceived advantage in the market. Bremelanotide is administered by subcutaneous injection. While the single-use, disposable autoinjector format is designed to maximize market acceptability, bremelanotide as a subcutaneous injectable drug for FSD may never achieve significant market acceptance. There is no drug approved in the United States for FSD, and thus actual market size and market dynamics are not known. We believe reimbursement of bremelanotide from third party payors such as health insurers, HMOs or other third-party payors of healthcare costs will be limited, and that the ultimate user will pay all or a substantial part of the cost of bremelanotide for FSD. We do not know the market price sensitivity of bremelanotide for FSD, or whether the market will support a product for FSD at the price range we project. If bremelanotide for FSD does not achieve adequate market acceptance at an acceptable price point, our business, financial condition and results of operations will 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.

[Back to Table of Contents](#)

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.

[Back to Table of Contents](#)

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.

[Back to Table of Contents](#)

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

We are developingbremelanotide for FSD, are in early stage development of other melanocortin receptor agonist compounds for sexual dysfunction and other indications and are developing 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 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. AstraZeneca may decide to abandon further development of this program, including terminating the agreement, if the results of further development efforts are negative or inconclusive, or if priorities within AstraZeneca change, or for any reason. Because 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 for any reason 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 forbremelanotide 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 forbremelanotide may be smaller than we anticipate. If it is smaller, it may be difficult for us to find marketing partners forbremelanotide, and our ability to generatebremelanotide 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 flibanserin, a daily-use oral drug being developed for hypoactive sexual desire disorder, and a number of daily-use oral and patch drugs incorporating testosterone. There is competition to develop drugs for treatment of FSD in both premenopausal and postmenopausal patients. Ourbremelanotide drug product is intended to be administered by subcutaneous injection, and an on-demand drug product for the same indication which utilizes another route of administration, such as a conventional oral drug product, may make subcutaneousbremelanotide 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 several products approved for use in treatment of obesity and related indications, and a number of other products being developed for treatment of obesity, including products in clinical trials. There is intense competition to develop drugs for treatment of obesity and related indications.

There are numerous products approved for use in treatment of 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.

[Back to Table of Contents](#)

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 third-party reimbursement might not be available for our proposed products once approved, or if obtained, might not be adequate.

There are no approved products for treating FSD, and thus there 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 bremelanotide for FSD will be classified as a Tier 3 drug, so that reimbursement will be limited for bremelanotide for treatment of FSD, assuming the product is approved by the FDA.

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.

[Back to Table of Contents](#)

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 brexelanotide clinical programs and our preclinical programs on an inhaled formulation of PL-3994 and 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.

[Back to Table of Contents](#)

We are authorized to issue up to 300,000,000 shares of common stock. To the extent that we sell or otherwise issue authorized but currently unissued 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 Placement

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 redeem Series A 2012 and Series B 2012 warrants at the option of the holders in the event of any takeover, change of control or other fundamental transaction which we permit.

Under the purchase agreement and form of warrants for our 2012 private placement, if we permit, make or allow a takeover, change of control or other fundamental transaction, including any transfer of all or substantially all of our properties or assets, then so long as any warrants remain outstanding we are required, as elected by the warrant holders, to pay such holders 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. The application of these provisions could adversely affect our financial position and 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 or change of control more costly.

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 these 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 or change of control more costly.

[Back to Table of Contents](#)

Risks Relating to Owning Our Common Stock

As of September 26, 2013, there were 96,153,887 shares of common stock underlying outstanding convertible preferred stock, options, restricted stock units and warrants. 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 26, 2013, 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;

3,821,303 shares issuable on the exercise of stock options, at exercise prices ranging from \$0.60 to \$42.10 per share;

646,250 shares issuable under restricted stock units which vest on dates between June 27, 2014 and June 27, 2015, subject to the fulfillment of service conditions; and

91,633,500 shares issuable on the exercise of warrants at exercise prices ranging from \$0.01 to \$3.30 per share, which includes warrants issued in our 2012 private placement for 67,476,531 shares issuable at an exercise price of \$0.01 per share.

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;

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.

[Back to Table of Contents](#)

For the 12 month period ended August 31, 2013, the price of our stock has been volatile, ranging from a high of \$1.10 per share to a low of \$0.51 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. Our outstanding Series A Preferred Stock, consisting of 4,697 shares on September 26, 2013, 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. 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.

Not applicable.

[Back to Table of Contents](#)

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, 2011.

FISCAL YEAR ENDED JUNE 30, 2013	HIGH	LOW
Fourth Quarter	\$ 0.79	\$ 0.51
Third Quarter	0.71	0.54
Second Quarter	1.10	0.53
First Quarter	1.20	0.45
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

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 26, 2013, we had approximately 217 record holders of common stock and the closing sales price of our common stock as reported on the NYSE MKT was \$0.70 per share.

Issuer purchases of equity securities. We have not and do not currently intend to retire or repurchase any of our capital securities other than providing our employees with the option to withhold shares to satisfy tax withholding amounts due from employees upon the vesting of restricted stock units in connection with our 2011 Stock Incentive Plan. The following 80,964 shares were withheld during the three-month period ended June 30, 2013 at the direction of the employees as permitted under the 2011 Stock Incentive Plan in order to pay the minimum amount of tax liability owed by the employee from the vesting of those units:

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares that May Yet be Purchased Under Announced Plans or Programs
April 1-31, 2013	—	—	—	—
May 1-30, 2013	—	—	—	—
June 1-30, 2013	80,964	\$0.65	—	—
Total	80,964	\$0.65	—	—

(1) Consists solely of 80,964 shares that were withheld to satisfy tax withholding amounts due from employees upon the vesting of previously issued

restricted stock units.

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 26, 2013, 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.

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.

[Back to Table of Contents](#)

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.

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. 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, 2013 Compared to the Year Ended June 30, 2012:

Revenue – For the fiscal year ended June 30, 2013 (fiscal 2013), we recognized \$10,000 in revenue, compared to \$74,000 for the fiscal year ended June 30, 2012 (fiscal 2012), pursuant to our license agreement with AstraZeneca. Revenue consisted entirely of reimbursement of development costs and per-employee compensation, earned at the contractual rate. We may also earn contract revenue based on the attainment of development milestones.

Research and Development – Research and development expenses decreased to \$10.5 million for fiscal 2013 compared to \$13.8 million for fiscal 2012. This decrease is primarily the result of costs relating to our Phase 2B clinical trial evaluating the efficacy and safety of bremelanotide for the treatment of FSD.

[Back to Table of Contents](#)

Research and development expenses related to our bremelanotide, PL-3994, peptide melanocortin agonist, obesity and other preclinical programs were \$7.6 million and \$9.9 million in fiscal years 2013 and 2012, respectively. The majority of spending was related to our Phase 2B clinical trial evaluating the efficacy and safety of bremelanotide for the treatment of FSD. We are currently completing protocols and preparing for initiation of pivotal Phase 3 studies of 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 amounts of project spending above exclude general research and development spending, which decreased to \$2.9 million for fiscal 2013 compared to \$3.9 million for fiscal 2012. The decrease is the result of closing our research laboratory operations in connection with the lease expiration of our laboratory facilities in July 2012.

Cumulative spending from inception to June 30, 2013 on our bremelanotide, NeutroSpec (a previously marketed imaging product which has been terminated) and other programs (which includes PL-3994, other melanocortin receptor agonists, obesity and other discovery programs) amounts to approximately \$163.6 million, \$55.6 million and \$61.0 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 were \$5.1 million for fiscal 2013 compared to \$5.0 million for fiscal 2012. These expenses mainly consist of compensation and related costs.

Other Income (Expense) – Other income (expense) was \$(7.0) million and \$0.5 million for fiscal 2013 and fiscal 2012, respectively. Fiscal 2013 other expense included the recognition of \$7.0 million non-cash charged for the increase in the fair value of warrants related to the July 3, 2012 private placement offering. Fiscal 2012 other income included a gain on disposition of supplies and equipment of \$0.4 million compared to \$5,000 for fiscal 2013. This increase is a result of closing our research laboratory facilities in July 2012. For fiscal 2013 we recognized \$43,000 of investment income compared to \$32,000 of investment income for fiscal 2012.

Income Tax Benefit – Income tax benefits of \$1.8 million in fiscal 2013 and \$1.1 million in fiscal 2012 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, 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 was primarily the result of costs relating to our then 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 was 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 and other programs (which includes PL-3994, other melanocortin receptor 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.

[Back to Table of Contents](#)

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.

Other Income (Expense) – Other income was \$0.5 million and \$0.2 million for fiscal 2012 and fiscal 2011, respectively. This increase was attributable to the gain on disposition of supplies and equipment of \$0.4 million as a result of closing our research laboratory facilities in July 2012 compared to a loss on disposition of supplies and equipment of \$6,000 for fiscal 2011. Fiscal 2011 also included a \$0.1 million gain on securities. For fiscal 2012 we recognized \$32,000 of investment income compared to \$0.1 million for fiscal 2011.

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.

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 (GMPs);

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 2013, we used \$13.6 million of cash for our operating activities, compared to \$15.5 million used in fiscal 2012 and \$11.0 million used in fiscal 2011. Lower net cash outflows from operations in fiscal 2013 compared to fiscal 2012 were primarily the result of decreased costs relating to our Phase 2B clinical trial evaluating the efficacy and

safety of bremelanotide for the treatment of FSD, while higher net cash outflows from operations in fiscal 2012 compared to fiscal 2011 resulted primarily from lower revenues and the increased costs relating to our Phase 2B clinical trial of bremelanotide for the treatment of FSD. 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.

[Back to Table of Contents](#)

During fiscal 2013, net cash used in investing activities was \$5.3 million, consisting of \$6.0 million used for the purchase of short-term investments, \$60,000 used for capital expenditures offset by the maturity of \$750,000 of short-term investments and \$5,000 in proceeds from the sale of equipment. 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 2013, cash provided by financing activities of \$34.3 million consisted primarily of the net proceeds from the completion of our private placement on July 3, 2012 offset by payments on capital lease obligations of \$22,000 and payment of withholding taxes related to restricted stock units of \$87,000. The private placement 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. Aggregate gross proceeds to us were \$35.0 million, with net proceeds, after deducting offering expenses, of \$34.4 million. 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 warrants to purchase 2,000,000 shares of our common stock, and Series B warrants to purchase 21,000,000 shares of our 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, 2013, our cash, cash equivalents and short-term investments were \$24.4 million and our current liabilities were \$2.1 million.

We intend to utilize existing capital resources for general corporate purposes and working capital, including preparing for the Phase 3 clinical trial program with bremelanotide for FSD, preclinical development of our peptide MC1R program, preclinical and clinical development of our PL-3994 program and preclinical development of other portfolio products. We believe that the Phase 3 clinical trial program with bremelanotide will cost at least \$78.0 million. We do not intend to initiate patient enrollment in the Phase 3 program unless we have adequate funds, or commitments for adequate funds, to complete the Phase 3 program. We intend to seek additional capital to support the Phase 3 program through collaborative arrangements on bremelanotide, public or private equity or debt financings, or other sources.

We believe that our existing capital resources will be adequate to fund our currently planned operations, including submitting complete protocols for pivotal Phase 3 studies to the U.S. Food and Drug Administration (FDA) but not initiating patient enrollment, through at least calendar year 2014.

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, 2013:

	Total	Payments due by Period			
		Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Facility operating leases	\$ 472,670	\$ 236,335	\$ 236,335	\$ -	\$ -
Capital lease obligations	20,615	20,615	-	-	-
Total contractual obligations	\$ 493,285	\$ 256,950	\$ 236,335	\$ -	\$ -

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

[Back to Table of Contents](#)

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:

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	30
<u>Consolidated Balance Sheets</u>	31
<u>Consolidated Statements of Operations</u>	32
<u>Consolidated Statements of Comprehensive Loss</u>	33
<u>Consolidated Statements of Stockholders' Equity</u>	34
<u>Consolidated Statements of Cash Flows</u>	35
<u>Notes to Consolidated Financial Statements</u>	36

[Back to Table of Contents](#)

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of Palatin Technologies, Inc. and subsidiary as of June 30, 2013 and 2012, and the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended June 30, 2013. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Palatin Technologies, Inc. and subsidiary as of June 30, 2013 and 2012, and the results of their operations and their cash flows for each of the years in the three-year period ended June 30, 2013, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Philadelphia, Pennsylvania
September 27, 2013

[Back to Table of Contents](#)

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Balance Sheets

	June 30, 2013	June 30, 2012
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 19,167,632	\$ 3,827,198
Short-term investments	5,249,654	-
Accounts receivable	-	27,631
Restricted cash	-	350,000
Prepaid expenses and other current assets	332,267	532,010
Total current assets	24,749,553	4,736,839
Property and equipment, net	266,415	318,653
Other assets	58,131	324,992
Total assets	\$ 25,074,099	\$ 5,380,484
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Capital lease obligations	\$ 19,909	\$ 22,277
Accounts payable	338,726	294,894
Accrued expenses	1,701,727	2,706,496
Accrued compensation	-	433,333
Total current liabilities	2,060,362	3,457,000
Capital lease obligations	-	19,909
Deferred rent	35,460	72,677
Total liabilities	2,095,822	3,549,586
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock of \$0.01 par value – authorized 10,000,000 shares; Series A Convertible; issued and outstanding 4,697 shares as of June 30, 2013 and 4,997 as of June 30, 2012	47	50
Common stock of \$0.01 par value – authorized 300,000,000 shares; issued and outstanding 39,116,948 shares as of June 30, 2013 and 34,900,591 as of June 30, 2012, respectively	391,169	349,006
Additional paid-in capital	282,692,520	240,725,127
Accumulated deficit	(260,105,459)	(239,243,285)
Total stockholders' equity	22,978,277	1,830,898
Total liabilities and stockholders' equity	\$ 25,074,099	\$ 5,380,484

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

[Back to Table of Contents](#)

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Statements of Operations

	Year Ended June 30,		
	2013	2012	2011
REVENUES:			
License and contract	\$ 10,361	\$ 73,736	\$ 497,540
Grant	-	-	977,917
	10,361	73,736	1,475,457
OPERATING EXPENSES:			
Research and development	10,528,691	13,813,376	10,377,019
General and administrative	5,066,830	5,045,741	4,751,824
Total operating expenses	15,595,521	18,859,117	15,128,843
Loss from operations	(15,585,160)	(18,785,381)	(13,653,386)
OTHER INCOME (EXPENSE):			
Investment income	42,734	32,133	99,258
Interest expense	(8,411)	(10,411)	(10,606)
Increase in fair value of warrants	(7,069,165)	-	(2,266)
Gain on sale of securities	-	-	119,346
Gain on disposition of supplies and equipment	4,620	442,248	(5,666)
Total other income (expense), net	(7,030,222)	463,970	200,066
Loss before income taxes	(22,615,382)	(18,321,411)	(13,453,320)
Income tax benefit	1,753,208	1,068,233	637,391
NET LOSS	\$(20,862,174)	\$(17,253,178)	\$(12,815,929)
Basic and diluted net loss per common share	\$(0.21)	\$(0.49)	\$(0.64)
Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share	97,618,714	34,900,591	20,084,022

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

[Back to Table of Contents](#)

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Statements of Comprehensive Loss

	Year Ended June 30,		
	2013	2012	2011
Net loss	\$(20,862,174)	\$(17,253,178)	\$(12,815,929)
Other comprehensive loss Unrealized loss on investments	-	-	(19,304)
Comprehensive loss	\$(20,862,174)	\$(17,253,178)	\$(12,835,233)

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

[Back to Table of Contents](#)

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Statements of Stockholders' Equity

	Preferred Stock		Common Stock		Additional	Accumulated Other		
	Shares	Amount	Shares	Amount	Paid-in Capital	Comprehensive Income	Accumulated Deficit	Total
Balance, June 30, 2010	4,997	\$50	11,702,818	\$117,028	\$218,236,723	\$138,650	\$(209,174,178)	\$9,318,273
Stock split adjustment for fractional shares	-	-	(46)	-	-	-	-	-
Sale of common stock units, net of costs	-	-	23,000,000	230,000	15,688,150	-	-	15,918,150
Reclassification of warrants from liability to equity	-	-	-	-	5,115,130	-	-	5,115,130
Exercise of warrants	-	-	32,200	322	64,078	-	-	64,400
Stock-based compensation	-	-	183,500	1,835	754,762	-	-	756,597
Payment of withholding taxes related to restricted stock units	-	-	(17,881)	(179)	(26,017)	-	-	(26,196)
Realized gain on sale of securities	-	-	-	-	-	(119,346)	-	(119,346)
Unrealized loss on investments	-	-	-	-	-	(19,304)	-	(19,304)
Net loss	-	-	-	-	-	-	(12,815,929)	(12,815,929)
Balance, June 30, 2011	4,997	50	34,900,591	349,006	239,832,826	-	(221,990,107)	18,191,775
Stock-based compensation	-	-	-	-	892,301	-	-	892,301
Net loss	-	-	-	-	-	-	(17,253,178)	(17,253,178)
Balance, June 30, 2012	4,997	50	34,900,591	349,006	240,725,127	-	(239,243,285)	1,830,898
Stock-based compensation	-	-	500,000	5,000	620,031	-	-	625,031
Sale of common stock,	-	-	3,873,000	38,730	17,403,075	-	-	17,441,805

net of costs									
Reclassification									
of warrants									
from liability									
to equity	-	-	-	-	24,030,128	-	-	24,030,128	
Payment of									
withholding									
taxes related to									
restricted									
stock units	-	-	(158,264)	(1,583)	(85,828)	-	-	(87,411)	
Series A									
Conversion	(300)	(3)	1,621	16	(13)	-	-	-	
Net loss	-	-	-	-	-	-	(20,862,174)	(20,862,174)	
Balance, June									
30, 2013	4,697	\$47	39,116,948	\$391,169	\$282,692,520	\$-	\$(260,105,459)	\$22,978,277	

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

[Back to Table of Contents](#)

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Statements of Cash Flows

	Year Ended June 30,		
	2013	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	\$(20,862,174)	\$(17,253,178)	\$(12,815,929)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	111,844	949,542	1,138,183
Accrued interest and amortization on premium/discount	(1,365)	-	-
Gain on sale of available-for-sale investments	-	-	(119,346)
Gain on disposition of supplies and equipment	(4,620)	(442,248)	5,666
Stock-based compensation	625,031	892,301	756,597
Increase in fair value of warrants	7,069,165	-	2,266
Changes in operating assets and liabilities:			
Accounts receivable	27,631	103,518	(128,270)
Prepaid expenses, restricted cash and other assets	816,605	(340,268)	263,280
Accounts payable	43,832	(202,014)	341,113
Accrued expenses, compensation and deferred rent	(1,475,319)	851,550	(519,899)
Unearned revenue	-	(46,105)	46,105
Net cash used in operating activities	(13,649,370)	(15,486,902)	(11,030,234)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Proceeds from sale/maturity of investments	750,000	-	3,442,885
Proceeds from sale of supplies and equipment	4,620	494,384	5,300
Purchases of property and equipment	(59,607)	(15,000)	-
Purchases of investments	(5,998,289)	-	-
Net cash (used in) provided by investing activities	(5,303,276)	479,384	3,448,185
CASH FLOWS FROM FINANCING ACTIVITIES:			
Payments on capital lease obligations	(22,277)	(34,923)	(22,960)
Payment of withholding taxes related to restricted stock units	(87,411)	-	(26,196)
Proceeds from sale of common stock units	34,402,768	-	21,095,414
Net cash provided by (used in) financing activities	34,293,080	(34,923)	21,046,258
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS			
	15,340,434	(15,042,441)	13,464,209
CASH AND CASH EQUIVALENTS, beginning of year	3,827,198	18,869,639	5,405,430
CASH AND CASH EQUIVALENTS, end of year	\$19,167,632	\$3,827,198	\$18,869,639
SUPPLEMENTAL CASH FLOW INFORMATION:			
Cash paid for interest	\$8,411	\$9,984	\$10,606
Equipment acquired under financing arrangements	-	-	66,115
Unrealized loss on available-for-sale investments	-	-	(19,304)

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

[Back to Table of Contents](#)

PALATIN TECHNOLOGIES, INC.
and Subsidiary

Notes to Consolidated Financial Statements

(1) ORGANIZATION:

Nature of Business – Palatin Technologies, Inc. (Palatin or the Company) is a biopharmaceutical company developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential. Palatin's programs are based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. 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, cachexia (wasting syndrome) and inflammation-related diseases. The natriuretic peptide receptor system has numerous cardiovascular functions, and therapeutic agents modulating this system may be useful in treatment of acute asthma, heart failure, hypertension and other cardiovascular diseases.

The Company's primary product in development is bremelanotide for the treatment of female sexual dysfunction (FSD). The Company also has drug candidates or development programs for obesity, erectile dysfunction, pulmonary diseases, cardiovascular diseases, dermatologic diseases and inflammatory diseases. The Company has an exclusive global research collaboration and license agreement with AstraZeneca AB (AstraZeneca) to commercialize compounds that target melanocortin receptors for the treatment of obesity, diabetes and related metabolic syndrome.

Key elements of the Company's business strategy include using its technology and expertise to develop and commercialize therapeutic products; entering into alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of product candidates that the Company is developing; and partially funding its product candidate development programs with the cash flow generated from the Company's license agreements with AstraZeneca and any other companies.

Business Risk and Liquidity – The Company has incurred negative cash flows from operations since its inception, and has expended, and expects to continue to expend in the future, substantial funds to complete its planned product development efforts. As shown in the accompanying consolidated financial statements, the Company had an accumulated deficit as of June 30, 2013 of \$260.1 million and incurred a net loss for fiscal 2013 of \$20.9 million. The Company anticipates incurring additional losses in the future as a result of spending on its development programs. To achieve profitability, the Company, alone or with others, must successfully develop and commercialize its technologies and proposed products, conduct successful 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 there can be no assurance that the Company will be able to achieve profitability on a sustained basis, if at all.

As of June 30, 2013, the Company's cash, cash equivalents and short-term investments were \$24.4 million. The Company intends to utilize existing capital resources for general corporate purposes and working capital, including preparing for the Phase 3 clinical trial program with bremelanotide for FSD, preclinical development of its peptide melanocortin receptor-1 program, preclinical and clinical development of its PL-3994 program and preclinical development of other portfolio products. Management believes that the Phase 3 clinical trial program with bremelanotide will cost at least \$78.0 million. The Company does not intend to initiate patient enrollment in the Phase 3 program unless the Company has adequate funds, or commitments for adequate funds, to complete the Phase 3 program. The Company intends to seek additional capital to support the Phase 3 program through collaborative arrangements on bremelanotide, public or private equity or debt financings, or other sources.

Management believes that the Company's existing capital resources will be adequate to fund its currently planned operations, including submitting complete protocols for pivotal Phase 3 studies to the U.S. Food and Drug Administration (FDA) but not initiating patient enrollment, through at least calendar year 2014.

Concentrations – Concentrations in the Company's assets and operations subject it to certain related risks. Financial instruments that subject the Company to concentrations of credit risk primarily consist of cash, cash equivalents and investments. The Company's cash and cash equivalents are primarily invested in one money market fund sponsored by a large financial institution and the Company's investments are invested in U.S government securities. For each of the years in the three-year period ended June 30, 2013, all license and contract revenues were from AstraZeneca.

[Back to Table of Contents](#)

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Principles of Consolidation – The consolidated financial statements include the accounts of Palatin and its wholly-owned inactive subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates – The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents – Cash and cash equivalents include cash on hand, cash in banks and all highly liquid investments with a purchased maturity of less than three months. Cash equivalents consist of \$16,284,184 and \$3,344,146 in a money market fund at June 30, 2013 and 2012, respectively.

Investments – The Company determines the appropriate classification of its investments in debt and equity securities at the time of purchase and reevaluates such determinations at each balance sheet date. Debt securities are classified as held-to-maturity when the Company has the intent and ability to hold the securities to maturity. Debt securities for which the Company does not have the intent or ability to hold to maturity are classified as available-for-sale. Held-to-maturity securities are recorded as either short-term or long-term on the balance sheet, based on the contractual maturity date and are stated at amortized cost. Marketable securities that are bought and held principally for the purpose of selling them in the near term are classified as trading securities and are reported at fair value, with unrealized gains and losses recognized in earnings. Debt and marketable equity securities not classified as held-to-maturity or as trading are classified as available-for-sale and are carried at fair market value, with the unrealized gains and losses, net of tax, included in the determination of comprehensive loss.

The fair value of substantially all securities is determined by quoted market prices. The estimated fair value of securities for which there are no quoted market prices is based on similar types of securities that are traded in the market.

Fair Value of Financial Instruments – The Company's financial instruments consist primarily of cash equivalents, short-term investments, accounts receivable, accounts payable and capital lease obligations. Management believes that the carrying values of these assets and liabilities are representative of their respective fair values based on quoted market prices for investments and the short-term nature of the other instruments.

Property and Equipment – Property and equipment consists of office and laboratory equipment, office furniture and leasehold improvements and includes assets acquired under capital leases. Property and equipment are recorded at cost. Depreciation is recognized using the straight-line method over the estimated useful lives of the related assets, generally five years for laboratory and computer equipment, seven years for office furniture and equipment and the lesser of the term of the lease or the useful life for leasehold improvements. Amortization of assets acquired under capital leases is included in depreciation expense. Maintenance and repairs are expensed as incurred while expenditures that extend the useful life of an asset are capitalized.

Impairment of Long-Lived Assets – The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. To determine recoverability of a long-lived asset, management evaluates whether the estimated future undiscounted net cash flows from the asset are less than its carrying amount. If impairment is indicated, the long-lived asset would be written down to fair value. Fair value is determined by an evaluation of available price information at which assets could be bought or sold, including quoted market prices, if available, or the present value of the estimated future cash flows based on

reasonable and supportable assumptions.

Deferred Rent – The Company’s operating leases provide for rent increases over the terms of the leases. Deferred rent consists of the difference between periodic rent payments and the amount recognized as rent expense on a straight-line basis, as well as tenant allowances for leasehold improvements. Rent expenses are being recognized ratably over the terms of the leases.

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 over the related performance period. The Company estimates the performance period as the period in which it performs certain development activities under the applicable agreement. Reimbursements for research and development activities are recorded in the period that the Company performs 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 the Company provides the services stipulated in the underlying grants based on the time and materials incurred.

[Back to Table of Contents](#)

Research and Development Costs – The costs of research and development activities are charged to expense as incurred, including the cost of equipment for which there is no alternative future use.

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 Company charges to expense the fair value of stock options and other equity awards granted. The Company determines the value of stock options utilizing the Black-Scholes option pricing model. Compensation costs for share-based awards with pro-rata vesting are allocated to periods on a straight-line basis.

Income Taxes – The Company and its subsidiary file consolidated federal and separate-company state income tax returns. Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax basis and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences or operating loss and tax credit carryforwards are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that includes the enactment date. The Company has recorded a valuation allowance against its deferred tax assets based on the history of losses incurred.

During the years ended June 30, 2013, 2012 and 2011, the Company sold New Jersey state net operating loss carryforwards, which resulted in the recognition of \$1,753,208, \$1,068,233, and \$637,391, respectively, in tax benefits.

Net Loss per Common Share – Basic and diluted earnings per common share (EPS) are calculated in accordance with the provisions of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 260, “Earnings per Share,” which includes guidance pertaining to the warrants, issued in connection with the July 3, 2012 private placement offering, that are exercisable for nominal consideration and, therefore, are to be considered in the computation of basic and diluted net loss per common share. The Series A 2012 warrants to purchase up to 31,988,151 shares of common stock were exercisable starting at July 3, 2012 and, therefore, are included in the weighted average number of common shares outstanding used in computing basic and diluted net loss per common share starting on July 3, 2012.

The Series B 2012 warrants to purchase up to 35,488,380 shares of common stock were considered contingently issuable shares and were not included in computing basic net loss per common share until the Company received stockholder approval for the increase in authorized underlying common stock on September 27, 2012 (see note 10). For diluted EPS, contingently issuable shares are to be included in the calculation as of the beginning of the period in which the conditions were satisfied, unless the effect would be anti-dilutive. The Series B 2012 warrants have been excluded from the calculation of diluted net loss per common share during the period from July 3, 2012 until September 27, 2012 as the impact would be anti-dilutive.

As of June 30, 2013, 2012 and 2011, there were 29,136,527, 27,179,180, and 27,130,580 common shares issuable upon conversion of Series A Convertible Preferred Stock, the exercise of outstanding options and warrants (excluding the warrants issued in connection with the July 3, 2013 private placement offering), and the vesting of restricted stock units, respectively. These share amounts have been excluded from the calculation of net loss per share as the impact

would be anti-dilutive.

(3) NEW AND RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

In June 2011, the FASB issued an update to its authoritative guidance which allows only two options for presenting the components of net loss and other comprehensive loss: (1) in a single continuous financial statement or (2) in two separate but consecutive financial statements. The guidance is effective in two stages. The requirements to present a single continuous statement or two separate but consecutive statements was effective for us beginning July 1, 2012. The second stage requires us to disclose the effects of reclassification adjustments from other comprehensive loss to net loss and is effective for us on July 1, 2013. For items reclassified in their entirety, we are required to disclose the effect of the reclassification on each line of net loss that is affected by the reclassification adjustment. For items not reclassified in their entirety, we are required to add a cross reference to the U.S. generally accepted accounting principles disclosure that includes additional information about the effect of the reclassification. The adoption of these updates affect presentation only and therefore did not impact our results of operations, financial condition or cash flows.

[Back to Table of Contents](#)

(4) AGREEMENT WITH ASTRAZENECA

In January 2007, the Company entered into an exclusive global 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 2008, the license agreement was amended to include additional compounds and associated intellectual property developed by the Company. In December 2008, the license agreement was further amended to include additional compounds and associated intellectual property developed by the Company and extended the research collaboration for an additional year through January 2010. In September 2009, the license agreement was further amended to modify royalty rates and milestone payments. The collaboration is based on the Company's melanocortin receptor obesity program and includes access to compound libraries, core technologies and expertise in melanocortin receptor drug discovery and development. As part of the September 2009 amendment to the research collaboration and license agreement, the Company agreed to conduct additional studies on the effects of melanocortin receptor specific compounds on food intake, obesity and other metabolic parameters.

In December 2009 and 2008, the Company also entered into clinical trial sponsored research agreements with AstraZeneca, under which the Company agreed to conduct studies of the effects of melanocortin receptor specific compounds on food intake, obesity and other metabolic parameters. Under the terms of these clinical trial agreements, AstraZeneca paid \$5,000,000 as of March 31, 2009 upon achieving certain objectives and paid all costs associated with these studies. The Company recognized \$10,361, \$73,736, and \$497,540, respectively, as revenue in the years ended June 30, 2013, 2012 and 2011 under these clinical trial sponsored research agreements.

The Company received an up-front payment of \$10,000,000 from AstraZeneca on execution of the research collaboration and license agreement. Under the September 2009 amendment the Company was paid an additional \$5,000,000 in consideration of reduction of future milestones and royalties and providing specific materials to AstraZeneca. The Company is now eligible for milestone payments totaling up to \$145,250,000, with up to \$85,250,000 contingent on development and regulatory milestones and the balance contingent on achievement of sales targets. In addition, the Company is eligible to receive mid to high single digit royalties on sales of any approved products. AstraZeneca assumed responsibility for product commercialization, product discovery and development costs, with both companies contributing scientific expertise in the research collaboration. The Company provided research services to AstraZeneca through January 2010, the expiration of the research collaboration portion of the research collaboration and license agreement, at a contractual rate per full-time-equivalent employee.

(5) FAIR VALUE MEASUREMENTS

The fair value of cash equivalents and short-term investments are classified using a hierarchy prioritized based on inputs. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on management's own assumptions used to measure assets and liabilities at fair value. A financial asset or liability's classification within the hierarchy is determined based on the lowest level input that is significant to the fair value measurement.

[Back to Table of Contents](#)

The following table provides the assets carried at fair value:

	Carrying Value	Quoted prices in active markets (Level 1)	Other quoted/observable inputs (Level 2)	Significant unobservable inputs (Level 3)
June 30, 2013:				
Money Market Fund	\$16,284,184	\$16,284,184	\$ -	\$ -
U.S. Government Securities	5,249,654	5,249,160	-	-
TOTAL	\$21,533,838	\$21,533,344	\$ -	\$ -
June 30, 2012:				
Money Market Fund	\$3,344,146	\$3,344,146	\$ -	\$ -

(6) PROPERTY AND EQUIPMENT, NET

Property and equipment, net, consists of the following:

	June 30, 2013	June 30, 2012
Office equipment	\$ 1,180,210	\$ 1,157,553
Laboratory equipment	311,369	317,418
Leasehold improvements	751,226	7,088,462
	2,242,805	8,563,433
Less: Accumulated depreciation and amortization	(1,976,390)	(8,244,780)
	\$ 266,415	\$ 318,653

In connection with the lease expiration in July 2012 of the Company's 28,000 square foot research and development facility, the Company abandoned fully depreciated leasehold improvements with a cost basis of \$6,352,411.

The aggregate cost of assets acquired under capital leases was \$66,115 as of June 30, 2013 and \$152,765 as of June 30, 2012. Accumulated amortization associated with assets acquired under capital leases was \$27,548 as of June 30, 2013 and \$100,975 as of June 30, 2012.

(7) ACCRUED EXPENSES

Accrued expenses consist of the following:

	June 30, 2013	June 30, 2012
Clinical study costs	\$ 1,054,270	\$ 1,752,392
Other research related expenses	186,241	253,968
Professional services	208,731	444,601
Insurance premiums payable	125,671	130,973
Other	126,814	124,562
	\$ 1,701,727	\$ 2,706,496

[Back to Table of Contents](#)

(8) COMMITMENTS AND CONTINGENCIES

Operating Leases – Effective January 31, 2011, the Company terminated the lease on 12,000 square feet of laboratory space in another building in the same center as the Company’s corporate offices and research and development facilities, which lease would have otherwise terminated in February 2012. Under the lease termination agreement the Company paid a \$60,000 termination fee, which was charged to expense. Effective July 31, 2012, the lease on 28,000 square feet of the Company’s research and development facilities expired. The Company currently leases facilities under a non-cancelable operating leases, which expires in June 2015. Future minimum lease payments under these leases are as follows:

Year Ending June 30,	
2014	\$ 236,335
2015	236,335
	\$ 472,670

For the years ended June 30, 2013, 2012 and 2011, rent expense was \$372,754, \$915,469, and \$1,242,708, respectively.

Capital Leases – The Company has acquired certain of its equipment under leases classified as capital leases. Scheduled future payments related to capital leases as of June 30, 2013 are as follows:

Year Ending June 30,	
2014	\$ 20,615
Amount representing interest	(706)
Net	\$ 19,909

Employment Agreements – The Company has employment agreements with two executive officers which provide a stated annual compensation amount, subject to annual increases, and annual bonus compensation in an amount to be approved by the Company’s Board of Directors. Each agreement allows the Company or the employee to terminate the agreement in certain circumstances. In some circumstances, early termination by the Company may result in severance pay to the employee for a period of 18 to 24 months at the salary then in effect, continuation of health insurance premiums over the severance period and immediate vesting of all stock options and restricted stock units. Termination following a change in control will result in a lump sum payment of one and one-half to two times the salary then in effect and immediate vesting of all stock options and restricted stock units.

Employee Retirement Savings Plan – The Company maintains a defined contribution 401(k) plan for the benefit of its employees. The Company currently matches a portion of employee contributions to the plan. For the years ended June 30, 2013, 2012 and 2011, Company contributions were \$150,256, \$124,351, and \$153,780, respectively.

Contingencies – The Company accounts for litigation losses in accordance with ASC 450-20, “Loss Contingencies.” Under ASC 450-20, loss contingency provisions are recorded for probable losses when management is able to reasonably estimate the loss. Any outcome upon settlement that deviates from the Company’s best estimate may result in additional expense or in a reduction in expense in a future accounting period. The Company records legal expenses associated with such contingencies as incurred.

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

(9) GRANT REVENUE

In October 2010, the Company was awarded \$977,917 in grants under the Patient Protection and Affordable Care Act of 2010. The grants related to four of the Company's projects: melanocortin agonists for sexual dysfunction; melanocortin agonists for obesity and related metabolic syndrome; natriuretic peptide mimetic PL-3994 for acute asthma; and subcutaneously-delivered natriuretic peptide mimetic PL-3994 for cardiovascular disease.

[Back to Table of Contents](#)

(10) STOCKHOLDERS' EQUITY

Series A Convertible Preferred Stock – As of June 30, 2013, 4,697 shares of Series A Convertible Preferred Stock were outstanding. Each share of Series A Convertible Preferred Stock is convertible at any time, at the option of the holder, into the number of shares of common stock equal to \$100 divided by the Series A Conversion Price. As of June 30, 2013, the Series A Conversion Price was \$8.89, so each share of Series A Convertible Preferred Stock is currently convertible into approximately 11.25 shares of common stock. The Series A Conversion Price is subject to adjustment, under certain circumstances, upon the sale or issuance of common stock for consideration per share less than either (i) the Series A Conversion Price in effect on the date of such sale or issuance, or (ii) the market price of the common stock as of the date of such sale or issuance. The Series A Conversion Price is also subject to adjustment upon the occurrence of a merger, reorganization, consolidation, reclassification, stock dividend or stock split which will result in an increase or decrease in the number of shares of common stock outstanding. Shares of Series A Convertible Preferred Stock have a preference in liquidation, including certain merger transactions, of \$100 per share, or \$469,700 in the aggregate as of June 30, 2013. Additionally, the Company may not pay a dividend or make any distribution to holders of any class of stock unless the Company first pays a special dividend or distribution of \$100 per share to holders of the Series A Convertible Preferred Stock.

Common Stock Transactions – On July 3, 2012, the Company closed on a private placement offering in which the Company sold, for aggregate proceeds of \$35.0 million, 3,873,000 shares of its common stock, Series A 2012 warrants to purchase up to 31,988,151 shares of common stock, and Series B 2012 warrants to purchase up to 35,488,380 shares of common stock. These warrants are exercisable at an exercise price of \$0.01 per share, and expire ten years from the date of issuance. The holders may exercise the warrants on a cashless basis. The warrants are subject to a blocker provision prohibiting exercise of the warrants if the holder and its affiliates would beneficially own in excess of 9.99% of the total number of shares of common stock of the Company following such exercise (as may be adjusted to the extent set forth in the warrant). The warrants also provide that in the event of a Company Controlled Fundamental Transaction (as defined in the warrants), the Company may, at the election of the warrant holder, be required to redeem all or a portion of the warrants at an amount tied to the greater of the then market price of the Company's common stock or the amount per share paid to any other person.

Because there were not sufficient authorized shares to cover all the outstanding Series B 2012 warrants in the private placement offering as of closing, under ASC 815, "Derivatives and Hedging," the portion of the warrants above the then authorized level of common stock was required to be classified as a liability and carried at fair value on the Company's balance sheet. The fair value, including the initial fair value liability of \$16,960,963, was calculated by multiplying the number of shares underlying the Series B 2012 warrants above the then authorized level of the Company's common stock by the closing price of its common stock less the exercise price of \$0.01 per share. The warrants were liability classified through September 27, 2012, at which time the then fair value of the warrant liability was reclassified into stockholders' equity upon stockholder approval of the increase in authorized common stock. The increase in fair value, as a result of the Company's common stock increasing from \$0.50 per share at date of issuance to \$0.71 per share upon shareholder approval, of \$7,069,165 has been recorded as a non-operating expense for the year ended June 30, 2013.

The purchase agreement for the private placement provides that the purchasers, funds under the management of QVT Financial LP, have certain rights until July 3, 2018, including rights of first refusal and participation in any subsequent equity or debt financing, provided that the funds own at least 20% of the outstanding common stock of the Company calculated as if warrants held by the funds were exercised. The purchase agreement also contains certain restrictive covenants so long as the funds continue to hold specified amounts of warrants or beneficially own specified amounts of the outstanding shares of common stock.

The net proceeds to the Company were \$34.4 million, after deducting offering expenses payable by the Company and excluding the proceeds to the Company, if any, from the exercise of the warrants issued in the offering.

On March 1, 2011, the Company closed on a firm commitment public offering in which the Company sold 23,000,000 shares of its common stock, Series A Warrants to purchase up to 2,000,000 shares of its common stock, and Series B Warrants to purchase up to 21,000,000 shares of its common stock. The Series A Warrants are exercisable starting March 1, 2011 at an exercise price of \$1.00 per share and are exercisable at any time until March 1, 2016. The Series B Warrants become exercisable starting on March 2, 2012 at an exercise price of \$1.00 per share and are exercisable at any time until March 2, 2017.

Gross proceeds from this offering were \$23,000,000, and net proceeds to the Company, after deducting underwriting discounts and other offering expenses, were \$21,031,014. In connection with the offering, the Company also issued warrants to the underwriters as part of their compensation to purchase up to 575,000 shares of the Company's common stock which become exercisable starting on March 2, 2012 at an exercise price of \$1.00 per share and are exercisable at any time until February 23, 2016.

[Back to Table of Contents](#)

Because there was not an adequate level of authorized shares to cover all the outstanding warrants in the firm commitment public offering as of closing, under ASC 815, “Derivatives and Hedging,” the portion of the warrants above the then authorized level of common stock were required to be classified as a liability and carried at their current fair value on the Company’s balance sheet. The fair value was estimated using the Black-Scholes option-pricing model. The warrants were revalued through May 11, 2011, the date the warrants ceased to be classified as a liability upon stockholder approval of the increase in authorized common stock, at which time the then fair value of the warrant liability was reclassified into stockholders’ equity. The increase in fair value of \$2,266 from the date of issuance through May 11, 2011 has been recorded as a non-operating expense.

Outstanding Stock Purchase Warrants – As of June 30, 2013, the Company had outstanding warrants exercisable for shares of common stock as follows:

Shares of Common Stock	Exercise Price per Share	Latest Termination Date
317,776	\$ 3.00	August 30, 2013
50,000	0.75	January 24, 2014
331,969	3.30	August 12, 2014
50,000	0.60	November 9, 2014
50,000	1.00	November 9, 2014
100,000	1.50	November 9, 2014
575,000	1.00	February 23, 2016
2,000,000	1.00	March 1, 2016
21,000,000	1.00	March 2, 2017
31,988,151	0.01	July 3, 2022
35,488,380	0.01	September 27, 2022
91,951,276		

During the fiscal year ended June 30, 2012, the Company issued warrants to consultants as part of their compensation to purchase up to 350,000 shares of the Company’s common stock. These warrants vest at various times and under certain conditions through November 2012. For the years ended June 30, 2013 and 2012, the Company recorded stock-based compensation related to these warrants of \$26,000 and \$41,134, respectively.

In August 2010, the Company received \$64,400 and issued 32,200 shares of common stock pursuant to the exercise of warrants at an exercise price of \$2.00 per share.

Stock Plan – The Company’s 2011 Stock Incentive Plan was approved by the Company’s stockholders at the annual meeting of stockholders held in May 2011 and amended at the annual meeting of stockholders held on June 27, 2013. The 2011 Stock Incentive Plan provides for incentive and nonqualified stock option grants and other stock-based awards to employees, non-employee directors and consultants for up to 7,000,000 shares of common stock. The 2011 Stock Incentive Plan is administered under the direction of the Board of Directors, which may specify grant terms and recipients. Options granted by the Company generally expire ten years from the date of grant and generally vest over three to four years. The 2005 Stock Plan was terminated and replaced by the 2011 Stock Incentive Plan, and shares of common stock that were available for grant under the 2005 Stock Plan became available for grant under the 2011 Stock Incentive Plan. No new awards can be granted under the 2005 Stock Plan, but awards granted under the 2005 Stock Plan remain outstanding in accordance with their terms. As of June 30, 2013, 2,936,331 shares were available for grant under the 2011 Stock Incentive Plan.

The Company also has outstanding options that were granted under a previous plan. The Company expects to settle option exercises under any of its plans with authorized but currently unissued shares.

[Back to Table of Contents](#)

The following table summarizes option activity for the years ended June 30, 2013, 2012 and 2011:

	2013		2012		2011	
	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
Outstanding at beginning of year	2,181,853	\$3.50	2,231,898	\$4.05	957,374	\$13.20
Granted	1,807,300	0.65	75,000	0.65	1,576,275	0.93
Forfeited	(74,985)	5.20	(90,870)	3.64	(234,951)	10.02
Exercised	-	-	-	-	-	-
Expired	(62,720)	11.91	(34,175)	33.07	(66,800)	41.14
Outstanding at end of year	3,851,448	1.99	2,181,853	3.50	2,231,898	4.05
Exercisable at end of year	1,673,973	3.64	1,323,965	5.10	809,918	9.28
Weighted average grant-date fair value of options granted during the year		\$0.56		\$0.47		\$0.77

The following table summarizes options outstanding as of June 30, 2013:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Term in Years	Aggregate Intrinsic Value
Options outstanding at end of year	3,851,448	\$1.99	8.2	\$400
Options vested and exercisable at end of year	1,673,973	\$3.64	6.8	\$-
Unvested options expected to vest	1,976,752	\$0.73	9.3	\$287

The fair value of option grants is estimated at the grant date using the Black-Scholes model. For grants during the year ended June 30, 2013, the Company's weighted average assumptions for expected volatility, dividends, term and risk-free interest rate were 101%, 0%, 8.6 years and 1.8%, respectively. For grants during the year ended June 30, 2012, the Company's weighted average assumptions for expected volatility, dividends, term and risk-free interest rate were 103%, 0%, 5.0 years and 0.92%, respectively. For grants during the year ended June 30, 2011, the Company's weighted average assumptions for expected volatility, dividends, term and risk-free interest rate were 100%, 0%, 8.7 years and 2.9%, respectively. Expected volatilities are based on the Company's historical volatility. The expected term of options is based upon the simplified method, which represents the average of the vesting term and the contractual term. The risk-free interest rate is based on U.S. Treasury yields for securities with terms approximating the expected term of the option.

For the years ended June 30, 2013, 2012 and 2011 the Company recorded stock-based compensation related to stock options of \$379,264, \$533,445 and \$437,480, respectively. The Company did not record a tax benefit related to stock-based compensation expense. As of June 30, 2013, there was \$1,113,107 of unrecognized compensation cost

related to unvested options, which is expected to be recognized over a weighted-average period of 1.4 years.

[Back to Table of Contents](#)

In June 2013, the Company granted 525,000 options to its executive officers, 394,300 options to its employees and 270,000 options to its non-employee directors under the Company's 2011 Stock Incentive Plan. The Company will amortize the fair value of these options of \$287,000, \$204,000 and \$148,000, respectively, over the 48 month vesting period ending June 30, 2017.

In July 2012, the Company granted 285,000 options to its executive officers, 182,500 options to its employees and 112,500 options to its non-employee directors under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these options of \$182,000, \$108,000 and \$72,000, respectively, over the 48 month vesting period ending July 31, 2016.

Restricted Stock Units – The following table summarizes restricted stock award activity for the years ended June 30, 2013, 2012 and 2011:

	2013	2012	2011
Outstanding at beginning of year	250,000	500,000	-
Granted	757,500	-	705,000
Forfeited	-	-	(21,500)
Vested	(250,000)	(250,000)	(183,500)
Outstanding at end of year	757,500	250,000	500,000

In June 2013, the company granted 420,000 restricted stock units to its executive officers and 115,000 restricted stock units to employees under the Company's 2011 Stock Incentive Plan. The Company will amortize the fair value of these restricted stock units of \$260,000 and \$71,000, respectively, over the 24 month vesting period ending June 30, 2015.

In July 2012, the Company granted 222,500 restricted stock units to its executive officers under the Company's 2011 Stock Incentive Plan. The Company is amortizing the fair value of these restricted stock units of \$160,000 over the 24 months ending July 2014. The Company recognized \$114,659 of stock-based compensation expense related to these restricted stock units during the year ended June 30, 2013.

In June 2011, the Company granted 500,000 restricted stock units to its executive management under the Company's 2011 Stock Incentive Plan. The grant date fair value of these restricted stock units of \$430,000 is being amortized over the 24 month vesting period of the award. The Company recognized \$105,108, \$317,722 and \$7,167, respectively, of stock-based compensation expense related to these restricted stock units during the years ended June 30, 2013, 2012 and 2011, respectively.

In July 2010, the Company granted 205,000 restricted stock units to its employees under the Company's 2005 Stock Plan of which 183,500 shares of common stock vested during fiscal 2011 with the balance forfeited. The Company recognized \$311,950 of stock-based compensation expense related to these restricted stock units during the year ended June 30, 2011.

In connection with the vesting of restricted share units during the years ended June 30, 2013, 2012 and 2011, the Company withheld 158,264, 0 and 17,881 shares with aggregate values of \$87,411, 0 and \$26,196, respectively, in satisfaction of minimum tax withholding obligations.

(11) INCOME TAXES

The Company has had no income tax expense or benefit since inception because of operating losses, except for amounts recognized for sales of New Jersey state net operating loss carryforwards. Deferred tax assets and liabilities are determined based on the estimated future tax effect of differences between the financial statement and tax

reporting basis of assets and liabilities, as well as for net operating loss carryforwards and research and development credit carryforwards, given the provisions of existing tax laws.

As of June 30, 2013, the Company had federal and state net operating loss carryforwards of approximately \$222,000,000 and \$101,000,000, respectively, which expire between 2013 and 2033 if not utilized. As of June 30, 2013, the Company had federal research and development credits of approximately \$6,600,000 that will begin to expire in 2013, if not utilized.

[Back to Table of Contents](#)

The Tax Reform Act of 1986 (the Act) provides for limitation on the use of net operating loss and research and development tax credit carryforwards following certain ownership changes (as defined by the Act) that could limit the Company's ability to utilize these carryforwards. The Company may have experienced various ownership changes, as defined by the Act, as a result of past financings. Accordingly, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes; therefore, the Company may not be able to take full advantage of these carryforwards for federal income tax purposes.

The Company's net deferred tax assets are as follows:

	June 30, 2013	June 30, 2012
Net operating loss carryforwards	\$ 83,470,000	\$ 81,460,000
Research and development tax credits	6,605,000	6,364,000
Accrued expenses, deferred revenue and other	1,698,000	3,969,000
	91,773,000	91,793,000
Valuation allowance	(91,773,000)	(91,793,000)
Net deferred tax assets	\$ -	\$ -

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and the application of loss limitation provisions related to ownership changes. Due to the Company's history of losses, the deferred tax assets are fully offset by a valuation allowance as of June 30, 2013 and 2012.

During the years ended June 30, 2013, 2012 and 2011, the Company sold New Jersey state net operating loss carryforwards, which resulted in the recognition of \$1,753,208, \$1,068,233, and \$637,391, respectively, in tax benefits.

[Back to Table of Contents](#)

(12) CONSOLIDATED QUARTERLY FINANCIAL DATA – UNAUDITED

The following tables provide quarterly data for the years ended June 30, 2013 and 2012:

	Three Months Ended			
	June 30, 2013	March 31, 2013	December 31, 2012	September 30, 2012
	(amounts in thousands, except per share data)			
Revenues	\$-	\$-	\$7	\$3
Operating expenses	4,720	4,024	3,447	3,404
Other income/(expense), net	2	9	11	(7,052)
Loss before income taxes	(4,718)	(4,015)	(3,429)	(10,453)
Income tax benefit	-	-	1,753	-
Net loss	\$(4,718)	\$(4,015)	\$(1,676)	\$(10,453)
Basic and diluted net loss per common share	\$(0.04)	\$(0.04)	\$(0.02)	\$(0.15)
Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share	106,435,741	106,424,443	106,424,443	71,669,170

	Three Months Ended			
	June 30, 2012	March 31, 2012	December 31, 2011	September 30, 2011
	(amounts in thousands, except per share data)			
Revenues	\$11	\$24	\$12	\$27
Operating expenses	5,702	6,050	3,713	3,394
Other income/(expense), net	438	6	8	12
Loss before income taxes	(5,253)	(6,020)	(3,693)	(3,355)
Income tax benefit	-	-	1,068	-
Net loss	\$(5,253)	\$(6,020)	\$(2,625)	\$(3,355)
Basic and diluted net loss per common share	\$(0.14)	\$(0.17)	\$(0.08)	\$(0.10)
Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share	34,900,591	34,900,591	34,900,591	34,900,591

[Back to Table of Contents](#)

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Our management carried out an evaluation, with the participation of our chief executive officer and our chief financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) of the Exchange Act) as of the end of the period covered by this report. Based upon this evaluation, our chief executive officer and our chief financial officer concluded that, as of June 30, 2013, our disclosure controls and procedures were effective.

A control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) or 15d-15(f) of the Exchange Act. Our internal control system was designed to provide reasonable assurance to management and the board of directors regarding the preparation and fair presentation of published financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

There was no change in our internal control over financial reporting during the fourth quarter of the period covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management assessed the effectiveness of our internal control over financial reporting as of June 30, 2013. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on its assessment, management believes that, as of June 30, 2013, our internal control over financial reporting is effective based on those criteria.

ITEM 9B. OTHER INFORMATION.

None.

[Back to Table of Contents](#)

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Identification of Directors

The following table sets forth the names, ages, positions and committee memberships of our directors. All directors hold office until the next annual meeting of stockholders or until their successors have been elected and qualified. All current directors were elected at our annual stockholders' meeting on June 27, 2013.

Name	Age	Position with Palatin
Carl Spana, Ph.D.	51	Chief executive officer, president and a director
John K.A. Prendergast, Ph.D.	59	Director, chairman of the board of directors
Perry B. Molinoff, M.D. (1) (3)	73	Director
Robert K. deVeer, Jr. (1) (2)	67	Director
Zola P. Horovitz, Ph.D. (2) (3)	78	Director
Robert I. Taber, Ph.D. (1) (2)	77	Director
J. Stanley Hull (3)	61	Director
Alan W. Dunton, M.D. (1) (2)	59	Director
Angela Rossetti (3)	60	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Corporate Governance Committee.

CARL SPANA, Ph.D., co-founder of Palatin, has been our chief executive officer and president since June 14, 2000. He has been a director of Palatin since June 1996 and has been a director of our wholly-owned subsidiary, RhoMed Incorporated, since July 1995. From June 1996 through June 14, 2000, Dr. Spana served as an executive vice president and our chief technical officer. From June 1993 to June 1996, Dr. Spana was vice president of Paramount Capital Investments, LLC, a biotechnology and biopharmaceutical merchant banking firm, and of The Castle Group Ltd., a medical venture capital firm. Through his work at Paramount Capital Investments and The Castle Group, Dr. Spana co-founded and acquired several private biotechnology firms. From July 1991 to June 1993, Dr. Spana was a Research Associate at Bristol-Myers Squibb, a publicly-held pharmaceutical company, where he was involved in scientific research in the field of immunology. He was previously a member of the board of the life science company AVAX Technologies, Inc. Dr. Spana received his Ph.D. in molecular biology from The Johns Hopkins University and his B.S. in biochemistry from Rutgers University.

Dr. Spana's qualifications for our board include his leadership experience, business judgment and industry experience. As a senior executive of Palatin for over fifteen years, he provides in-depth knowledge of our company, our drug products under development and the competitive and corporate partnering landscape.

JOHN K.A. PRENDERGAST, Ph.D., co-founder of Palatin, has been chairman of the board since June 14, 2000, and a director since August 1996. Dr. Prendergast has been president and sole stockholder of Summercloud Bay, Inc., an independent consulting firm providing services to the biotechnology industry, since 1993. Dr. Prendergast is a director and executive chairman of the board of directors of Antyra, Inc., a privately-held biopharmaceutical firm. He was previously a member of the board of the life science companies AVAX Technologies, Inc., Avigen, Inc. and MediciNova, Inc. From October 1991 through December 1997, Dr. Prendergast was a managing director of The Castle Group Ltd., a medical venture capital firm. Dr. Prendergast received his M.Sc. and Ph.D. from the University of New South Wales, Sydney, Australia and a C.S.S. in administration and management from Harvard University.

Dr. Prendergast brings a historical perspective to our board coupled with extensive industry experience in corporate development and finance in the life sciences field. His prior service on other publicly traded company boards provides experience relevant to good corporate governance practices.

[Back to Table of Contents](#)

PERRY B. MOLINOFF, M.D. has been a director since November 2001. He served as our executive vice president for research and development from September 2001 until November 3, 2003, when he resigned to accept a position as Vice Provost for Research at the University of Pennsylvania, which he held from November 2003 through September 2006. He was a director of Cypress Bioscience, Inc., a publicly-held life science company, from 2004 through its acquisition in 2010. In May 2012 he became a director of Cynapsus Therapeutics Inc., a publicly-held Canadian specialty pharmaceutical company. Dr. Molinoff has more than 30 years of experience in both the industrial and educational sectors. From 1981 to 1994, he was a professor of pharmacology and chairman of the Department of Pharmacology at the University of Pennsylvania School of Medicine in Philadelphia. From January 1995 until March 2001, he was vice president of neuroscience and genitourinary drug discovery for the Bristol-Myers Squibb Pharmaceutical Research Institute, where he was responsible for directing and implementing the Institute's research efforts. Dr. Molinoff earned his medical degree from Harvard Medical School.

Dr. Molinoff has extensive academic and pharmaceutical company experience, with scientific knowledge that makes him a resource to our executive officers and other board members. As a former officer of Palatin, Dr. Molinoff has significant knowledge of our technologies and drug products under development, as well as the markets potentially addressed by our drug products under development.

ROBERT K. deVEER, Jr. has been a director since November 1998. Since January 1997, Mr. deVeer has been the president of deVeer Capital LLC, a private investment company. He was a director of Solutia Inc., a publicly-held chemical-based materials company, until its merger with Eastman Chemical Company in July 2012. From 1995 until his retirement in 1996, Mr. deVeer served as Managing Director, Head of Industrial Group, at New York-based Lehman Brothers. From 1973 to 1995, he held increasingly responsible positions at New York-based CS First Boston, including Head of Project Finance, Head of Industrials and Head of Natural Resources. He was a managing director, member of the investment banking committee and a trustee of the First Boston Foundation. He received a B.A. in economics from Yale University and an M.B.A. in finance from Stanford Graduate School of Business.

Mr. deVeer has extensive experience in investment banking and corporate finance, including the financing of life sciences companies, and serves as the audit committee's financial expert.

ZOLA P. HOROVITZ, Ph.D. has been a director since February 2001. Before he retired from Bristol-Myers Squibb in 1994, Dr. Horovitz spent 34 years in various positions, including associate director of the Squibb Institute for Medical Research, vice president of development, vice president, scientific liaison, vice president of licensing, and vice president of business development and planning for the pharmaceutical division of Bristol-Myers Squibb. He held advisory positions at the University of Pittsburgh, Rutgers College of Pharmacy and Princeton University. He is currently a director and non-executive chairman of the board of GenVec, Inc., a publicly-held life science company. Within the past five years, Dr. Horovitz also served on the board of directors of BioCryst Pharmaceutical, Inc., Genaera Corp., Immunicon Corp., NitroMed, Inc., Avigen, Inc. and DOV Pharmaceutical, Inc. Dr. Horovitz earned his Ph.D. in pharmacology from the University of Pittsburgh.

Dr. Horovitz has extensive experience in development of pharmaceutical drugs, business development and licensing, and has served on the board of directors of a number of publicly-held life science companies.

ROBERT I. TABER, Ph.D. has been a director since May 2001. Dr. Taber began his career in the pharmaceutical industry in 1962, holding a succession of positions within Schering Corporation's biological research group before leaving in 1982 as director of biological research. He has also held a number of increasingly important positions with DuPont Pharmaceuticals and the DuPont Merck Pharmaceutical Company, including director of pharmaceutical research, director of pharmaceutical and biotechnology research, vice president of pharmaceutical research and vice president of extramural research and development. From 1994 to 1998, Dr. Taber held the position of senior vice president of research and development at Synaptic Pharmaceuticals Corporation before founding Message

Pharmaceuticals, Inc. in 1998, serving as president and chief executive officer until 2000. Dr. Taber earned his Ph.D. in pharmacology from the Medical College of Virginia.

Dr. Taber has extensive experience in pharmaceutical research and development both in large pharmaceutical companies and in smaller biotechnology and biopharmaceutical companies.

J. STANLEY HULL has been a director since September 2005. Mr. Hull has over three decades of experience in the field of sales and marketing. Mr. Hull joined GlaxoSmithKline, a research-based pharmaceutical company, in October 1987 and retired as Senior Vice President, Pharmaceuticals in May 2010, having previously served in the R&D organization of GlaxoSmithKline as Vice President and Worldwide Director of Therapeutic Development and Product Strategy – Neurology and Psychiatry. Prior to that, he was Vice President of Marketing – Infectious Diseases and Gastroenterology for Glaxo Wellcome Inc. Mr. Hull started his career in the pharmaceutical industry with SmithKline and French Laboratories in 1978. Mr. Hull received his B.S. in business administration from the University of North Carolina at Greensboro.

[Back to Table of Contents](#)

Mr. Hull has extensive experience in commercial operations, development and marketing of pharmaceutical drugs and corporate alliances between pharmaceutical companies and biotechnology companies.

ALAN W. DUNTON, M.D. has been a director since June 2011. Since April 2006, he has been president of Danerius, LLC, a biotechnology consulting company, which he founded in 2006. From January 2007 to March 2009, Dr. Dunton served as president and chief executive officer of Panacos Pharmaceuticals Inc. and he served as a managing director of Panacos from March 2009 to January 2011. Dr. Dunton is currently a member of the board of directors of the publicly-traded companies Oragenics, Inc. and Targacept, Inc. and the privately-held biotechnology company Sancilio and Company, Inc., and, within the past five years, he served on the board of directors of the publicly-traded companies EpiCept Corporation (acquired by Immune Pharmaceuticals, Inc.), Adams Respiratory Therapeutics, Inc. (acquired by Reckitt Benckiser Group plc), MediciNova, Inc. and Panacos Pharmaceuticals, Inc. Previously, Dr. Dunton served as a director or executive officer of various pharmaceutical companies, and from 1994 to 2001, Dr. Dunton was a senior executive in various capacities in the Pharmaceuticals Group of Johnson & Johnson. Dr. Dunton received his M.D. degree from New York University School of Medicine, where he completed his residency in internal medicine. He also was a Fellow in Clinical Pharmacology at the New York Hospital/Cornell University Medical Center.

Dr. Dunton has extensive drug development and clinical research experience, having played a key role in the development of more than 20 products to regulatory approval, and also has extensive experience as an executive or officer for large pharmaceutical companies and smaller biotechnology and biopharmaceutical companies.

ANGELA ROSSETTI has been a director since June 2013. From 2009 through January 2012, she was a vice president at Pfizer Inc., where she led a global commercial medicine team for a smoking cessation franchise. She was an assistant vice president at Wyeth, managing a global hemophilia franchise from 2007 until 2009, when Wyeth was acquired by Pfizer. From 2005 to 2006 she was president of Ogilvy Healthworld, an advertising business in the pharmaceutical and biotechnology sectors. Previously she worked in a variety of increasingly responsible positions in communications, marketing and venture capital/investment banking. Ms. Rossetti is currently a candidate for a master's degree in bioethics from Albert Einstein College of Medicine, and has an M.B.A. in finance from Columbia University Graduate School of Business and a B.A. from the University of Pennsylvania.

Ms. Rossetti has extensive experience in worldwide development and marketing of specialty pharmaceuticals, including prefilled syringe products, and in communications and development of marketing and promotional plans.

The Board and Its Committees

Committees and meetings. The board has an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. During fiscal 2013, the board met four times, the Audit Committee met four times, the Compensation Committee met twice and the Nominating and Corporate Governance Committee met once. Each director attended at least 75% of the total number of meetings of the board and committees of the board on which he served. With the exception of Drs. Prendergast and Spana, the directors did not attend the annual meeting of stockholders held on June 27, 2013.

Audit Committee. The Audit Committee reviews the engagement of the independent registered public accounting firm and reviews the independence of the independent registered public accounting firm. The Audit Committee also reviews the audit and non-audit fees of the independent registered public accounting firm and the adequacy of our internal control procedures. The Audit Committee is currently composed of four non-employee directors, Mr. deVeer (chair) and Drs. Taber, Molinoff and Dunton, all of whom are independent. The board has determined that the members of the Audit Committee are independent, as defined in the listing standards of the NYSE MKT, and satisfy the requirements of the NYSE MKT as to financial literacy and expertise. The board has determined that at least one

member of the committee, Mr. deVeer, is the audit committee financial expert as defined by Item 407 of Regulation S-K. The responsibilities of the Audit Committee are set forth in a written charter adopted by the board, a copy of which is available on our web site at www.palatin.com.

Compensation Committee. The Compensation Committee reviews and recommends to the board on an annual basis employment agreements and compensation for our officers, directors and some employees, and administers our 2011 Stock Incentive Plan and the options still outstanding which were granted under previous stock option plans. The Compensation Committee is composed of Mr. deVeer and Drs. Horovitz, Taber (chair) and Dunton. The board has determined that the members of the Compensation Committee are independent, as defined in the listing standards of the NYSE MKT.

[Back to Table of Contents](#)

The Board has adopted a charter for the Compensation Committee effective October 1, 2013, a copy of which is available on our web site at www.palatin.com. The committee administers our 2011 Stock Incentive Plan, under which it has delegated to an officer its authority to grant stock options to employees and to a single-member committee of the board its authority to grant restricted stock units to officers and to grant options and restricted stock units to our consultants, but in either instance not to grant options or restricted stock units to themselves, any member of the board or officer, or any person subject to Section 16 of the Exchange Act. Our chief financial officer supports the committee in its work by gathering, analyzing and presenting data on our compensation arrangements and compensation in the marketplace.

Nominating and Corporate Governance Committee. The Nominating and Corporate Governance Committee assists the board in recommending nominees for directors, and in determining the composition of committees. It also reviews, assesses and makes recommendations to the board concerning policies and guidelines for corporate governance, including relationships of the board, the stockholders and management in determining our direction and performance. The responsibilities of the Nominating and Corporate Governance Committee are set forth in a written charter adopted by the board, a copy of which is available on our web site at www.palatin.com. The Nominating and Corporate Governance Committee is composed of Mr. Hull, Drs. Horovitz (chair) and Molinoff and Ms. Rossetti, each of whom meets the independence requirements established by the NYSE MKT.

Duration of Office. Unless a director resigns, all directors hold office until the next annual meeting of stockholders or until their successors have been elected and qualified. Directors serve as members of committees as the board determines from time to time.

Stockholder Communication with Directors

Generally, stockholders who have questions or concerns should contact Stephen T. Wills, Secretary, Palatin Technologies, Inc., 4B Cedar Brook Drive, Cranbury, NJ 08512. However, any stockholder who wishes to address questions regarding our business directly to the board of directors, or any individual director, can direct questions to the board members or a director by regular mail to the Secretary at the address above or by e-mail at boardofdirectors@palatin.com. Stockholders may submit their concerns anonymously or confidentially by postal mail.

Communications are distributed to the board, or to any individual directors as appropriate, depending on the facts and circumstances outlined in the communication, unless the Secretary determines that the communication is unrelated to the duties and responsibilities of the board, such as product inquiries, resumes, advertisements or other promotional material. Communications that are unduly hostile, threatening, illegal or similarly unsuitable will also not be distributed to the board or any director. All communications excluded from distribution will be retained and made available to any non-management director upon request.

Code of Corporate Conduct and Ethics

We have adopted a code of corporate conduct and ethics that applies to all of our directors, officers and employees, including our chief executive officer and chief financial officer. You can view the code of corporate conduct and ethics at our website, www.palatin.com. We will disclose any amendments to, or waivers from, provisions of the code of corporate conduct and ethics that apply to our directors, principal executive and financial officers in a current report on Form 8-K, unless the rules of the NYSE MKT permit website posting of any such amendments or waivers.

Executive Officers

Executive officers are appointed by the board and serve at the discretion of the board. Each officer holds his position until his successor is appointed and qualified. The current executive officers hold office under employment

agreements.

Name	Age	Position with Palatin
Carl Spana, Ph.D.	51	Chief executive officer, president and director
Stephen T. Wills, MST, CPA	56	Chief financial officer, chief operating officer, executive vice president, secretary and treasurer

52

[Back to Table of Contents](#)

Additional information about Dr. Spana is included above under the heading “Identification of Directors.”

STEPHEN T. WILLS, MST, CPA, has been vice president, secretary, treasurer and chief financial officer since 1997 and was executive vice president of operations from 2005 until June 2011, when he was appointed chief operating officer and executive vice president. From July 1997 to August 2000, Mr. Wills was also a vice president and the chief financial officer of Derma Sciences, Inc., a publicly-held company which provides wound and skin care products, and currently serves as lead director of Derma. Mr. Wills is also a director and chair of the audit committee of Miami International Securities Exchange, LLC, a privately-held fully-electronic options and equities exchange currently in development, and within the past five years was a director of U.S. Helicopter Corp., a publicly-held company. From 1991 to August 2000, he was the president and chief operating officer of Golomb, Wills & Company, P.C., a public accounting firm. Mr. Wills, a certified public accountant, received his B.S. in accounting from West Chester University, and an M.S. in taxation from Temple University.

Section 16(A) Beneficial Ownership Reporting Compliance

The rules of the SEC require us to disclose failures to file or late filings of reports of stock ownership and changes in stock ownership required to be filed by our directors, officers and holders of more than 10% of our common stock. To the best of our knowledge, all of the filings for our directors, officers and holders of more than 10% of our common stock were made on a timely basis in fiscal 2013, except that one report on Form 4 relating to the open market purchase of common stock by Dr. Molinoff on December 24, 2012 was filed late.

ITEM 11. EXECUTIVE COMPENSATION.

Fiscal 2013 Summary Compensation Table

The following table summarizes the compensation earned by or paid to our principal executive officer and our principal financial officer for our fiscal years ended June 30, 2013 and 2012. We have no defined benefit or actuarial pension plan, and no deferred compensation plan.

Name and Principal Position	Fiscal Year	Salary (\$)	Stock awards (1) (\$)	Option awards (1) (\$)	Nonequity incentive plan compensation (2) (\$)	All other compensation (3) (\$)	Total (\$)
Carl Spana, Ph.D., chief executive officer and president	2013	436,771	217,400	245,971	250,000	12,938	1,163,080
	2012	420,000	-	-	112,500	12,750	545,250
Stephen T. Wills, MST, CPA, chief financial officer, chief operating officer and executive vice president	2013	394,167	203,200	222,742	225,000	13,000	1,058,109
	2012	375,000	-	-	105,000	13,375	493,375

- (1) Amounts in these columns represent the aggregate grant date fair value for stock awards and option awards computed using the Black-Scholes model.
For a description of the assumptions we used to calculate these amounts, see Note 10 to the consolidated financial statements included in this Annual Report.
- (2) Bonus amounts for fiscal 2013 were set by the board and paid in June 2013. Bonus amounts listed above as earned for fiscal 2012 were not paid out until July 2012 (that is, during fiscal 2013).
- (3) Consists of matching contributions to 401(k) plan.

[Back to Table of Contents](#)

Employment Agreements

Effective July 1, 2013, we entered into employment agreements with Dr. Spana and Mr. Wills which continue through June 30, 2016 unless terminated earlier. Under these agreements, which replaced substantially similar agreements that expired on June 30, 2013, Dr. Spana is serving as chief executive officer and president at a base salary of \$450,000 per year and Mr. Wills is serving as chief financial officer and chief operating officer at a base salary of \$410,000 per year. Each agreement also provides for:

annual discretionary bonus compensation, in an amount to be decided by the Compensation Committee and approved by the board, based on achievement of yearly objectives; and

participation in all benefit programs that we establish, to the extent the executive's position, tenure, salary, age, health and other qualifications make him eligible to participate.

Each agreement allows us or the executive to terminate the agreement upon written notice, and contains other provisions for termination by us for "cause," or by the employee for "good reason" or due to a "change in control" (as these terms are defined in the employment agreements and set forth below). Early termination may, in some circumstances, result in severance pay at the salary then in effect, plus continuation of medical and dental benefits then in effect for a period of two years (Dr. Spana) or 18 months (Mr. Wills). In addition, the agreements provide that options and restricted stock units granted to these officers accelerate upon termination of employment except for voluntary resignation by the officer or termination for cause. In the event of retirement, termination by the officer for good reason, or termination by us other than for "cause", options may be exercised until the earlier of twenty-four months following termination or expiration of the option term. Arrangements with our named executive officers in connection with a termination following a change in control are described below. Each agreement includes non-competition, non-solicitation and confidentiality covenants.

The Compensation Committee awarded bonuses to our named executive officers for fiscal 2013, paid in June 2013 and fiscal 2012, paid in July 2012, based on results of operations, including clinical trial operations and our financial condition.

Stock Option and Restricted Stock Unit Grants

The Compensation Committee determined that additional equity grants were necessary in order to motivate and retain our executive officers. On June 27, 2013, we granted 220,000 restricted stock units to Dr. Spana and 200,000 restricted stock units to Mr. Wills, which vest as to 50% on each anniversary of the grant date. We also granted 275,000 stock options to Dr. Spana and 250,000 stock options Mr. Wills, which vest as to 25% on each anniversary of the grant date. These options have an exercise price of \$0.62, the fair market value on the date of grant, and they expire on June 27, 2023.

Effective July 17, 2012, we granted 112,500 restricted stock units to Dr. Spana and 110,000 restricted stock units to Mr. Wills, which vest as to 50% on each anniversary of the grant date (subject to contractual limitations on vesting which expired on September 1, 2013). We also granted 150,000 stock options to Dr. Spana and 135,000 stock options to Mr. Wills, which vest as to 25% on each anniversary of the grant date (subject to contractual limitations on vesting which expired on September 1, 2013). These options have an exercise price of \$0.72, the fair market value on the date of grant, and they expire on July 17, 2022.

Vesting of both the restricted stock units and the options granted in 2012 and 2013 was limited by our agreements with QVT, but the limitations expired on September 1, 2013, on which date 50% of the restricted stock units granted in 2012 and 25% of the stock options granted in 2012 vested.

[Back to Table of Contents](#)

Outstanding Equity Awards at 2013 Fiscal Year-End

The following table summarizes all of the outstanding equity-based awards granted to our named executive officers as of June 30, 2013, the end of our fiscal year.

Name	Option or stock award grant date	Option awards (1)				Stock awards (2)	
		Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price (\$)	Option expiration date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested (\$) (3)
Carl Spana	07/16/03	10,000	-	32.40	07/16/13		
	07/01/05	7,500	-	37.50	07/01/15		
	07/01/05	8,300	-	17.50	07/01/15		
	10/06/06	12,500	-	24.90	10/06/16		
	03/26/08	28,125	-	2.80	03/26/18		
	03/26/08	4,687	-	5.00	03/26/18		
	03/26/08	4,688	-	6.60	03/26/18		
	07/01/08	25,000	-	1.80	07/01/18		
	07/01/09	18,750	6,250	2.80	07/01/19		
	06/22/11	150,000	150,000	1.00	06/22/21		
	07/17/12	-	150,000	0.72	07/17/22		
	07/17/12					112,500	69,750
	06/27/13	-	275,000	0.62	06/27/23		
	06/27/13					220,000	136,400
Stephen T. Wills	07/16/03	8,000	-	32.40	07/16/13		
	07/01/05	5,000	-	37.50	07/01/15		
	07/01/05	7,300	-	17.50	07/01/15		
	10/06/06	10,000	-	24.90	10/06/16		
	03/26/08	22,500	-	2.80	03/26/18		
	03/26/08	3,750	-	5.00	03/26/18		
	03/26/08	3,750	-	6.60	03/26/18		
	07/01/08	20,000	-	1.80	07/01/18		
	07/01/09	15,000	5,000	2.80	07/01/19		
	06/22/11	125,000	125,000	1.00	06/22/21		
	07/17/12	-	135,000	0.72	07/17/22		
	07/17/12					110,000	68,200
	06/27/13	-	250,000	0.62	06/27/23		
	06/27/13					200,000	124,000

(1) Stock option vesting schedules: all options granted on or before July 1, 2008 have fully vested. Options granted after July 1, 2008 vest over four years with 1/4 of the shares vesting per year starting on the first anniversary of the grant date, provided that the named executive officer remains an employee. See "Termination and Change-In-Control Arrangements" below.

- (2) Stock award vesting schedule: stock awards consist of restricted stock units granted on July 17, 2012, which vested as to 50% on September 1, 2013 and vest as to the remaining 50% on July 17, 2014, and restricted stock units granted on June 27, 2013, which vest as to 50% on June 27, 2014 and as to the remaining 50% on June 27, 2015, provided that the named executive officer remains an employee. See “Termination and Change-In-Control Arrangements” below.
- (3) Calculated by multiplying the number of restricted stock units by \$0.62, the closing market price of our common stock on June 28, 2013, the last trading day of our most recently completed fiscal year.

[Back to Table of Contents](#)

Termination and Change-In-Control Arrangements

The employment agreements, stock option agreements and restricted stock unit agreements with Dr. Spana and Mr. Wills contain the following provisions concerning severance compensation and the vesting of stock options and restricted stock units upon termination of employment or upon a change in control. The executive's entitlement to severance, payment of health benefits and accelerated vesting of options is contingent on the executive executing a general release of claims against us.

Termination Without Severance Compensation. Regardless of whether there has been a change in control, if we terminate employment for cause or the executive terminates employment without good reason (as those terms are defined in the employment agreement and set forth below), then the executive receives only his accrued salary and vacation benefits through the date of termination. He may also elect to receive medical and dental benefits pursuant to COBRA for up to two years (Dr. Spana) or 18 months (Mr. Wills), but must remit the cost of coverage to us. Under the terms of our outstanding options and restricted stock units, all unvested options and restricted stock units would terminate immediately, and vested options would be exercisable for three months after termination.

Severance Compensation Without a Change in Control. If we terminate or fail to extend the employment agreement without cause, or the executive terminates employment with good reason, then the executive will receive as severance pay his salary then in effect, paid in a lump sum, plus medical and dental benefits at our expense, for a period of two years (Dr. Spana) or 18 months (Mr. Wills) after the termination date. In addition, upon such event all unvested options would immediately vest and be exercisable for two years after the termination date or, if earlier, the expiration of the option term, and all unvested restricted stock units would accelerate and become fully vested.

Severance Compensation After a Change in Control. If, within one year after a change in control, we terminate employment or the executive terminates employment with good reason, then the executive will receive as severance pay 200% (Dr. Spana) or 150% (Mr. Wills) of his salary then in effect, paid in a lump sum, plus medical and dental benefits at our expense, for a period of two years (Dr. Spana) or 18 months (Mr. Wills) after the termination date. We would also reimburse the executive for up to \$25,000 in fees and expenses during the six months following termination, for locating employment. We would also reimburse the executive for any excise tax he might incur on "excess parachute payments" (as defined in Section 280G(b) of the Internal Revenue Code). All unvested options would immediately vest and be exercisable for two years after the termination date or, if earlier, the expiration of the option term. All unvested restricted stock units would vest upon a change in control, without regard to whether the executive's employment is terminated.

Option and Restricted Stock Unit Vesting Upon a Change in Control. Options and restricted stock units granted under the 2011 Stock Incentive Plan vest upon a change in control. If any options granted under the 2005 Stock Plan are to be terminated in connection with a change in control, those options will vest in full immediately before the change in control.

[Back to Table of Contents](#)

Definitions. Under the employment agreements, a “change in control,” “cause” and “good reason” are defined as follows:

A “change in control” occurs when:

- (a) some person or entity acquires more than 50% of the voting power of our outstanding securities;
- (b) the individuals who, during any twelve month period, constitute our board of directors cease to constitute at least a majority of the board of directors;
- (c) we enter into a merger or consolidation; or
- (d) we sell substantially all our assets.

The term “cause” means:

- (a) the occurrence of (i) the executive’s material breach of, or habitual neglect or failure to perform the material duties which he is required to perform under, the terms of his employment agreement; (ii) the executive’s material failure to follow the reasonable directives or policies established by or at the direction of our board of directors; or (iii) the executive’s engaging in conduct that is materially detrimental to our interests such that we sustain a material loss or injury as a result thereof, provided that the breach or failure of performance is not cured, to the extent cure is possible, within ten days of the delivery to the executive of written notice thereof;
- (b) the willful breach by the executive of his obligations to us with respect to confidentiality, invention and non-disclosure, non-competition or non-solicitation; or
- (c) the conviction of the executive of, or the entry of a pleading of guilty or nolo contendere by the executive to, any crime involving moral turpitude or any felony.

The term “good reason” means the occurrence of any of the following, with our failure to cure such circumstances within 30 days of the delivery to us of written notice by the executive of such circumstances:

- (a) any material adverse change in the executive’s duties, authority or responsibilities, which causes the executive’s position with us to become of significantly less responsibility, or assignment of duties and responsibilities inconsistent with the executive’s position;
- (b) a material reduction in the executive’s salary;
- (c) our failure to continue in effect any material compensation or benefit plan in which the executive participates, unless an equitable arrangement has been made with respect to such plan, or our failure to continue the executive’s participation therein (or in a substitute or alternative plan) on a basis not materially less favorable, both in terms of the amount of benefits provided and the level of the executive’s participation relative to other participants;
- (d) our failure to continue to provide the executive with benefits substantially similar to those enjoyed by the executive under any of our health and welfare insurance, retirement and other fringe-benefit plans, the taking of any action by us which would directly or indirectly materially reduce any of such benefits, or our failure to provide the executive with the number of paid vacation days to which he is entitled; or
- (e) the relocation of the executive to a location which is a material distance from Cranbury, New Jersey.

[Back to Table of Contents](#)

Director Compensation

The following table sets forth the compensation we paid to all directors during fiscal 2013, except for Dr. Spana, whose compensation is set forth above in the Summary Compensation Table and related disclosure. Dr. Spana did not receive any separate compensation for his services as a director.

Name (1)	Fees earned or paid in cash (\$)	Option awards (\$) (2)	Total (\$)
John K.A. Prendergast, Ph.D.	75,000	47,153	122,153
Perry B. Molinoff, M.D.	37,000	25,964	62,964
Robert K. deVeer, Jr.	43,500	25,964	69,464
Zola P. Horovitz, Ph.D.	37,500	25,964	63,464
Robert I. Taber, Ph.D.	42,000	25,964	67,964
J. Stanley Hull	32,000	25,964	57,964
Alan W. Dunton, M.D.	38,500	25,964	64,464
Angela Rossetti	-	16,411	16,411

(1) Ms. Rossetti did not serve as a director until her election on June 27, 2013. The aggregate number of shares underlying option awards outstanding at June 30, 2013 for each director was:

Dr. Prendergast	253,350
Dr. Molinoff	159,333
Mr. deVeer	157,000
Dr. Horovitz	153,500
Dr. Taber	153,500
Mr. Hull	152,166
Dr. Dunton	77,500
Ms. Rossetti	30,000

(2) Amounts in this column represent the aggregate grant date fair value for option awards computed using the Black-Scholes model. For a description of the assumptions we used to calculate these amounts, see Note 10 to the consolidated financial statements included in this Annual Report. Amounts in this column include options granted June 27, 2013 for our current (2014) fiscal year and options granted July 17, 2012 for our 2013 fiscal year.

Non-Employee Directors' Option Grants. Our non-employee directors receive an annual option grant at the board meeting closest to the beginning of each fiscal year, or such other date as may be determined by the board.

On June 27, 2013, as the annual option grant for our current (2014) fiscal year, the chairman of the board received an option to purchase 60,000 shares of common stock and each other serving non-employee director received an option to purchase 30,000 shares of common stock. All of these options have an exercise price of \$0.62 per share, the closing

price of our common stock on the date of grant, vest in twelve monthly installments beginning on July 31, 2013 (subject to limitations on vesting which expired on September 1, 2013), expire ten years from the date of grant and provide for accelerated vesting in the event of involuntarily termination as a director following a change in control, with exercise permitted following accelerated vesting for up to the earlier of one year after termination or the expiration date of the option.

On July 17, 2012, as the previously reported annual option grant for our 2013 fiscal year, the chairman of the board received an option to purchase 22,500 shares of common stock and each other serving non-employee director received an option to purchase 15,000 shares of common stock. All of these options have an exercise price of \$0.72 per share, the closing price of our common stock on the date of grant, vested in twelve monthly installments beginning on July 31, 2012 (subject to limitations on vesting which expired on September 1, 2013), expire ten years from the date of grant and provide for accelerated vesting in the event of involuntarily termination as a director following a change in control, with exercise permitted following accelerated vesting for up to the earlier of one year after termination or the expiration date of the option.

[Back to Table of Contents](#)

Non-Employee Directors' Cash Compensation. Dr. Prendergast serves as chairman of the board and for our 2013 fiscal year received an annual retainer of \$75,000, payable quarterly. Other non-employee directors received an annual base retainer of \$30,000, payable on a quarterly basis. The chairperson of the Audit Committee received an additional annual retainer of \$10,000, the chairperson of the Compensation Committee received an additional annual retainer of \$7,000 and the chairperson of the Corporate Governance Committee received an additional annual retainer of \$4,000. Members of the foregoing committees, other than the non-employee chairman, received an additional retainer of one-half the retainer payable to the committee chairperson.

Non-Employee Directors' Expenses. Non-employee directors are reimbursed for expenses incurred in performing their duties as directors, including attending all meetings of the board and any committees on which they serve.

Employee Directors. Employee directors are not separately compensated for services as directors, but are reimbursed for expenses incurred in performing their duties as directors, including attending all meetings of the board and any committees on which they serve.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

Securities Authorized for Issuance Under Equity Compensation Plans. The table below provides information on our equity compensation plans as of June 30, 2013:

Equity Compensation Plan Information
as of June 30, 2013

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	4,608,948 (1)	\$ 1.99	(2) 2,936,331
Equity compensation plans not approved by security holders	0	0	0
Total	4,608,948	\$ 1.99	2,936,331

(1) Consists of 3,292,150 options and 757,500 restricted stock units granted under our 2011 Stock Incentive Plan, 502,715 options granted under our 2005 Stock Plan and 56,583 options granted under our 1996 Stock Option Plan. Both our 2005 Stock Plan and 1996 Stock Option Plan have terminated, but termination does not affect awards that are currently outstanding under these plans. The shares subject to outstanding awards under the 2005 Stock Plan, if forfeited prior to exercise, will become available for issuance under the 2011 Stock Incentive Plan.

(2) The amount in column (a) for equity compensation plans approved by security holders includes 757,500 shares reserved for issuance on vesting of outstanding restricted stock units, granted under our 2011 Stock Incentive Plan,

which vest on various dates through June 27, 2015, subject to the fulfillment of service conditions. Because no exercise price is required for issuance of shares on vesting of the restricted stock units, the weighted-average exercise price in column (b) does not take the restricted stock units into account.

[Back to Table of Contents](#)

Beneficial Ownership Tables. The tables below show the beneficial stock ownership and voting power, as of September 26, 2013, of:

each director, each of the named executive officers, and all current directors and officers as a group; and

all persons who, to our knowledge, beneficially own more than five percent of the common stock or Series A preferred stock.

“Beneficial ownership” here means direct or indirect voting or investment power over outstanding stock and stock which a person has the right to acquire now or within 60 days after September 26, 2013. See the footnotes for more detailed explanations of the holdings. Except as noted, to our knowledge, the persons named in the tables beneficially own and have sole voting and investment power over all shares listed.

The common stock has one vote per share and the Series A preferred stock has approximately 11.25 votes per share. Voting power is calculated on the basis of the aggregate of common stock and Series A preferred stock outstanding as of September 26, 2013, on which date 39,191,655 shares of common stock and 4,697 shares of Series A preferred stock, convertible into 52,829 shares of common stock, were outstanding.

The address for all members of our management is c/o Palatin Technologies, Inc., 4B Cedar Brook Drive, Cranbury, NJ 08512. Addresses of other beneficial owners are in the table.

MANAGEMENT:

Class	Name of beneficial owner	Amount and nature of beneficial ownership		Percent of class	Percent of total voting power	
Common	Carl Spana, Ph.D.	679,141	(1)	1.7	%	*
Common	Stephen T. Wills	611,538	(2)	1.5	%	*
Common	John K.A. Prendergast, Ph.D.	195,117	(3)	*		*
Common	Perry B. Molinoff, M.D.	137,833	(4)	*		*
Common	Robert K. deVeer, Jr.	149,060	(5)	*		*
Common	Zola P. Horovitz, Ph.D.	134,000	(6)	*		*
Common	Robert I. Taber, Ph.D.	129,000	(7)	*		*
Common	J. Stanley Hull	124,166	(8)	*		*
Common	Alan W. Dunton, M.D.	55,020	(9)	*		*
Common	Angela Rossetti	10,000	(10)	*		*
		2,224,875	(11)	5.5	%	1.8 %

All current directors and executive officers as
a group (ten persons)

*Less than one percent.

- (1) Includes 303,300 shares which Dr. Spana has the right to acquire under options, and 50,000 shares which he has the right to acquire under Series A and Series B 2011 warrants.
- (2) Includes 251,050 shares which Mr. Wills has the right to acquire under options, and 50,000 shares which he has the right to acquire under Series A and Series B 2011 warrants.
- (3) Includes 193,350 shares which Dr. Prendergast has the right to acquire under options.
- (4) Includes 126,833 shares which Dr. Molinoff has the right to acquire under options.
- (5) Includes 127,000 shares which Mr. deVeer has the right to acquire under options.
- (6) Includes 123,500 shares which Dr. Horovitz has the right to acquire under options.

[Back to Table of Contents](#)

- (7) Includes 123,500 shares which Dr. Taber has the right to acquire under options.
- (8) Includes 122,166 shares which Mr. Hull has the right to acquire under options.
- (9) Includes 47,500 shares which Dr. Dunton has the right to acquire under options.
- (10) Shares which Ms. Rossetti has the right to acquire under options.
- (11) Includes 1,528,199 shares which directors and officers have the right to acquire under options and warrants.

MORE THAN 5% BENEFICIAL OWNERS:

Class	Name and address of beneficial owner	Amount and nature of beneficial ownership (1)	Percent of class	Percent of total voting power		
Common	Mark N. Lampert BVF Inc. BVF Partners L.P. 900 North Michigan Avenue Suite 1100 Chicago, Illinois 60611	5,200,000 (2)	13.3	%	13.3	%
Common	QVT Financial LP 1177 Avenue of the Americas, 9th Floor New York, New York 10036	3,919,935 (3)	9.9	%	9.9	%
Common	Great Point Partners LLC Jeffrey R. Jay, M.D. David Kroin 165 Mason Street, 3rd Floor Greenwich, CT 06830	4,057,092 (4)	9.9	%	6.7	%
Common	James E. Flynn 780 Third Avenue, 37th Floor New York, NY 10017	4,094,759 (5)	9.9	%	5.9	%
Common	First Eagle Investment Management, LLC 1345 Avenue of the Americas New York, NY 10105	2,298,660 (6)	5.6	%	2.0	%
Series A Preferred	Tokenhouse PTE LTD 9 – 11 Reitergasse Zurich 8027, Switzerland	667	14.2	%	*	
Series A Preferred	Steven N. Ostrovsky 43 Nikki Ct. Morganville, NJ 07751	500	10.6	%	*	

Series A Preferred	Thomas L. Cassidy IRA Rollover				
	38 Canaan Close				
Series A Preferred	New Canaan, CT 06840	500	10.6	%	*
Series A Preferred	Jonathan E. Rothschild				
	300 Mercer St., #28F				
Series A Preferred	New York, NY 10003	500	10.6	%	*

[Back to Table of Contents](#)

Class	Name and address of beneficial owner	Amount and nature of beneficial ownership (1)	Percent of class	Percent of total voting power	
Series A Preferred	Arthur J. Nagle 19 Garden Avenue Bronxville, NY 10708	250	5.3	%	*
Series A Preferred	Thomas P. and Mary E. Heiser, JTWROS 10 Ridge Road Hopkinton, MA 01748	250	5.3	%	*
Series A Preferred	Carl F. Schwartz 31 West 87th St. New York, NY 10016	250	5.3	%	*
Series A Preferred	Michael J. Wrubel 3650 N. 36 Avenue, #39 Hollywood, FL 33021	250	5.3	%	*
Series A Preferred	Myron M. Teitelbaum, M.D. 175 Burton Lane Lawrence, NY 11559	250	5.3	%	*
Series A Preferred	Laura Gold Galleries Ltd. Profit Sharing Trust Park South Gallery at Carnegie Hall 154 West 57th Street, Suite 114 New York, NY 10019-3321	250	5.3	%	*
Series A Preferred	Laura Gold 180 W. 58th Street New York, NY 10019	250	5.3	%	*

*Less than one percent.

(1) Unless otherwise indicated by footnote, all share amounts represent outstanding shares of the class indicated, and all beneficial owners listed have, to our knowledge, sole voting and dispositive power over the shares listed.

(2) According to a joint Schedule 13G/A filed on October 7, 2011, Mr. Lampert, BVF Partners L.P. and BVF, Inc. shared voting and dispositive power with respect to all the shares listed, and the other filers had beneficial ownership as follows, as to which Mr. Lampert, BVF Partners L.P. and BVF, Inc. disclaim beneficial ownership:

(i) BVF Investments, L.L.C.: 3,091,000 shares;

(ii) Biotechnology Value Fund, L.P.: 1,086,200 shares;

(iii) Biotechnology Value Fund II, L.P.: 667,900 shares; and

(iv) Investment 10, L.L.C.: 354,900 shares.

(3) Includes 46,935 shares issuable on exercise of Series A 2012 warrants. According to a joint Schedule 13G filed on July 10, 2012, QVT Financial LP (“QVT Financial”) is the investment manager for QVT Fund IV LP (“Fund IV”), which beneficially owns 501,360 shares of common stock, for QVT Fund V LP (“Fund V”), which beneficially owns 2,956,894 shares of common stock, and for Quintessence Fund L.P. (“Quintessence”), which beneficially owns 434,628 shares of common stock. QVT Financial has the power to direct the vote and disposition of the common stock held by Fund IV, Fund V and Quintessence. Accordingly, QVT Financial may be deemed to be the beneficial owner of an aggregate amount of 3,892,882 shares of common stock, consisting of the shares beneficially owned by Fund IV, Fund V and Quintessence.

[Back to Table of Contents](#)

QVT Financial GP LLC, as General Partner of QVT Financial, may be deemed to beneficially own the same number of shares of common stock reported by QVT Financial. QVT Associates GP LLC, as General Partner of Fund IV, Fund V and Quintessence, may be deemed to beneficially own the aggregate number of shares of common stock beneficially owned by Fund IV, Fund V and Quintessence, and accordingly, QVT Associates GP LLC may be deemed to be the beneficial owner of an aggregate amount of 3,892,882 shares of common stock.

Exercise of the Series A 2012 warrants and Series B 2012 warrants is restricted if, as a result of an exercise, the beneficial ownership of the holder and its affiliates and any other party or person that could be deemed to be a group would exceed 9.99% of the outstanding common stock (as may be adjusted to the extent set forth in the Series A 2012 warrants and Series B 2012 warrants). Beneficial ownership as listed in the table above excludes Series A 2012 warrants and Series B 2012 warrants which are not exercisable because of that restriction.

(4) Includes 1,419,885 shares issuable on exercise of warrants. Dr. Jay and Mr. Kroin are managing members of Great Point Partners, LLC. According to a joint Schedule 13G/A filed on February 14, 2013, each of the owners listed had shared voting and dispositive power with respect to all the shares listed. Great Point Partners, LLC is the investment manager for the following entities or persons, which have shared voting and dispositive power over the number of shares indicated:

- (i) Biomedical Value Fund, LP: 860,637 shares outstanding and 762,692 shares issuable on exercise of warrants;
- (ii) Biomedical Offshore Value Fund, Ltd.: 496,301 shares outstanding and 439,819 shares issuable on exercise of warrants;
- (iii) Biomedical Institutional Value Fund, LP: 319,131 shares outstanding and 282,815 shares issuable on exercise of warrants;
- (iv) Lyrical Multi-Manager Fund, LP: 299,998 shares outstanding and 265,834 shares issuable on exercise of warrants;
- (v) Lyrical Multi-Manager Fund Offshore Fund, Ltd.: 130,362 shares outstanding and 115,513 shares issuable on exercise of warrants;
- (vi) Class D Series of GEF-PS, LP: 430,362 shares outstanding and 381,347 shares issuable on exercise of warrants;
- (vii) David J. Morrison: 14,343 shares outstanding and 12,712 shares issuable on exercise of warrants; and
- (viii) WS Investments III, LLC: 86,073 shares outstanding and 76,269 shares issuable on exercise of warrants.

Exercise of the warrants is restricted if, as a result of exercise, the beneficial ownership of the holder or any group including the holder would exceed 9.99% of the outstanding common stock. Beneficial ownership as listed in the table above excludes warrants which are not exercisable because of that restriction.

(5) Includes 1,796,929 shares issuable on exercise of warrants. According to a joint Schedule 13G/A filed on February 14, 2013, Mr. Flynn and the other filers had beneficial ownership and shared voting and dispositive power as follows:

- (i) James E. Flynn: 2,297,830 shares outstanding and 3,250,000 shares issuable on exercise of warrants held by Deerfield Special Situations Fund, L.P. and Deerfield Special Situations Fund International Limited. Mr. Flynn shares voting and dispositive power over the shares owned by Deerfield Special Situations Fund, L.P. and Deerfield Special Situations Fund International Limited.

(ii) Deerfield Mgmt, L.P.: 2,297,830 shares outstanding and 3,250,000 shares issuable on exercise of warrants held by Deerfield Special Situations Fund, L.P. and Deerfield Special Situations International Master Fund, L.P., of which Deerfield Mgmt, L.P. is the general partner.

(iii) Deerfield Management Company, L.P.: 2,297,830 shares outstanding and 3,250,000 shares issuable on exercise of warrants held by Deerfield Special Situations Fund, L.P. and Deerfield Special Situations International Master Fund, L.P., of which Deerfield Management Company, L.P. is the investment advisor.

[Back to Table of Contents](#)

(iv) Deerfield Special Situations Fund L.P.: 1,057,000 shares outstanding and 1,287,000 shares issuable on exercise of warrants.

(v) Deerfield Special Situations International Master Fund, L.P.: 1,240,830 shares outstanding and 1,963,000 shares issuable on exercise of warrants.

Exercise of the warrants is restricted if, as a result of exercise, the beneficial ownership of the holder or any group including the holder would exceed 9.99% of the outstanding common stock. Beneficial ownership as listed in the table above excludes warrants which are not exercisable because of that restriction.

(6) Includes 1,525,020 shares issuable on exercise of warrants. According to a Schedule 13G/A filed on February 11, 2013, First Eagle Investment Management, LLC is deemed to be the beneficial owner of the shares listed as a result of acting as investment advisor to various clients, including First Eagle Value in Biotechnology Master Fund, Ltd., a Cayman Islands company, which may be deemed to beneficially own 773,660 shares outstanding and 762,500 shares issuable on exercise of warrants.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The board of directors has determined that all of the directors except for Dr. Spana (our chief executive officer and president) and Dr. Prendergast (our chairman) are independent directors, as defined in the listing standards of the NYSE MKT, on which our common stock is listed. All members of committees of the board are independent directors.

As a condition of employment, we require all employees to disclose in writing actual or potential conflicts of interest, including related party transactions. Our code of corporate conduct and ethics, which applies to employees, officers and directors, requires that the Audit Committee review and approve related party transactions. Since July 1, 2011, there have been no transactions or proposed transactions in which we were or are to be a participant, in which any related person had or will have a direct or indirect material interest.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

KPMG LLP (KPMG) served as our independent registered public accounting firm for fiscal 2013 and fiscal 2012.

Audit Fees. For fiscal 2013, we anticipate that KPMG will bill us a total of \$220,000 for professional services rendered for the audit of our annual consolidated financial statements, review of our consolidated financial statements in our Forms 10-Q and services provided in connection with regulatory filings. For fiscal 2012, the total billed for the same services was \$305,000.

Audit-Related Fees. For fiscal 2013 and 2012, KPMG did not perform or bill us for any audit-related services.

Tax Fees. For fiscal 2013, we anticipate that KPMG will bill us a total of \$15,500 for professional services rendered for tax compliance. For fiscal 2012, KPMG billed us \$15,500 for professional services rendered for tax compliance.

All Other Fees. KPMG did not perform or bill us for any services other than those described above for fiscal 2013 and 2012.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors. Consistent with SEC policies regarding auditor independence, the Audit Committee has responsibility for appointing,

setting compensation for and overseeing the work of the independent registered public accounting firm. In recognition of this responsibility, the Audit Committee has established a policy to pre-approve all audit and permissible non-audit services provided by the independent registered public accounting firm.

The Audit Committee pre-approves fees for each category of service. The fees are budgeted and the Audit Committee requires the independent registered public accounting firm and management to report actual fees versus the budget periodically throughout the year by category of service. During the year, circumstances may arise when it may become necessary to engage the independent registered public accounting firm for additional services not contemplated in the original pre-approval. In those instances, the Audit Committee requires specific pre-approval before engaging the independent registered public accounting firm.

The Audit Committee may delegate pre-approval authority to one or more of its members. The member to whom such authority is delegated must report, for informational purposes only, any pre-approval decisions to the Audit Committee at its next scheduled meeting.

[Back to Table of Contents](#)

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a) Documents filed as part of the report:

1. Financial statements: The following consolidated financial statements are filed as a part of this report under Item 8 – Financial Statements and Supplementary Data:

- Report of Independent Registered Public Accounting Firm
- Consolidated Balance Sheets
- Consolidated Statements of Operations
- Consolidated Statements of Stockholders' Equity and Comprehensive Loss
- Consolidated Statements of Cash Flows
- Notes to Consolidated Financial Statements

2. Financial statement schedules: None.

3. Exhibits:

No.	Description
3.01	Restated certificate of incorporation, as amended. *
3.02	Bylaws. Incorporated by reference to Exhibit 3.1 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2007, filed with the SEC on February 8, 2008.
4.01	Form of warrant issued to purchasers in our August 2009 registered direct offering. Incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed with the SEC on August 13, 2009.
4.02	Warrant Agreement dated as of March 1, 2011, between Palatin and American Stock Transfer & Trust Company, a New York limited liability trust company. Incorporated by reference to Exhibit 4.1 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on May 13, 2011.
4.03	Definitive form of Series A 2011 Warrant certificate pursuant to Palatin's effective registration statement No. 333-170227 on Form S-1. Incorporated by reference to Exhibit 4.2 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on May 13, 2011.
4.04	Definitive form of Series B 2011 Warrant certificate pursuant to Palatin's effective registration statement No. 333-170227 on Form S-1. Incorporated by reference to Exhibit 4.3 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on May 13, 2011.
4.05	

Definitive form of underwriters' warrant to purchase common stock pursuant to Palatin's effective registration statement No. 333-170227 on Form S-1. Incorporated by reference to Exhibit 4.4 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on May 13, 2011.

- 4.06 Warrant issued to Noble International Investments, Inc. at an exercise price of \$0.60 per share in connection with entering into a contract for financial advisory services. Incorporated by reference to Exhibit 4.1 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2011, filed with the SEC on February 14, 2012.
- 4.07 Form of warrant issued to Noble International Investments, Inc. at exercise prices of \$1.00 and \$1.50 per share in connection with entering into a contract for financial advisory services. Incorporated by reference to Exhibit 4.2 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2011, filed with the SEC on February 14, 2012.
- 4.08 Warrant issued to Chardan Capital Markets, LLC at an exercise price of \$0.75 per share in connection with entering into a contract for financial advisory services. Incorporated by reference to Exhibit 4.1 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, filed with the SEC on May 14, 2012.
- 4.09 Form of Series A 2012 common stock purchase warrant. Incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed with the SEC on July 6, 2012.

[Back to Table of Contents](#)

No.	Description
4.10	Form of Series B 2012 common stock purchase warrant. Incorporated by reference to Exhibit 4.2 of our Current Report on Form 8-K, filed with the SEC on July 6, 2012.
10.01	1996 Stock Option Plan, as amended. Incorporated by reference to Exhibit 10.01 of our Annual Report on Form 10-K for the year ended June 30, 2009, filed with the SEC on September 28, 2009. †
10.02	Form of Option Certificate (incentive option) under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed with the SEC on September 21, 2005. †
10.03	Form of Incentive Stock Option Agreement under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K, filed with the SEC on September 21, 2005. †
10.04	Form of Option Certificate (non-qualified option) under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.3 of our Current Report on Form 8-K, filed with the SEC on September 21, 2005. †
10.05	Form of Non-Qualified Stock Option Agreement under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.4 of our Current Report on Form 8-K, filed with the SEC on September 21, 2005. †
10.06	Research Collaboration and License Agreement dated January 30, 2007, between Palatin and AstraZeneca AB. Incorporated by reference to Exhibit 10.2 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2006, filed with the SEC on February 8, 2007. We have obtained confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
10.07	Palatin Technologies, Inc. 2007 Change in Control Severance Plan. Incorporated by reference to Exhibit 10.4 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2007, filed with the SEC on February 8, 2008. †
10.08	2005 Stock Plan, as amended December 7, 2007, March 10, 2009 and May 13, 2009. Incorporated by reference to Exhibit 10.1 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2009, filed with the SEC on May 15, 2009. †
10.09	Form of Executive Officer Option Certificate. Incorporated by reference to Exhibit 10.1 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed with the SEC on May 14, 2008. †
10.10	Form of Amended Restricted Stock Unit Agreement. Incorporated by reference to Exhibit 10.2 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed with the SEC on May 14, 2008. †
10.11	Form of Amended Option Certificate (incentive option) under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.3 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed with the SEC on May 14, 2008. †
10.12	First Amendment dated June 27, 2008 to the Research Collaboration and License Agreement between Palatin and AstraZeneca AB. Incorporated by reference to Exhibit 10.28 of our Annual Report on Form 10-K for the year ended June 30, 2008, filed with the SEC on September 29, 2008. We have obtained confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the

information subject to the confidentiality request.

- 10.13 Second Amendment dated December 5, 2008 to the Research Collaboration and License Agreement between Palatin and AstraZeneca AB. Incorporated by reference to Exhibit 10.2 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2008, filed with the SEC on February 13, 2009. We have obtained confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
- 10.14 Clinical Trial Sponsored Research Agreement dated December 5, 2008 to the Research Collaboration and License Agreement between Palatin and AstraZeneca AB. Incorporated by reference to Exhibit 10.3 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2008, filed with the SEC on February 13, 2009. We have obtained confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
- 10.15 Form of securities purchase agreement for our August 2009 registered direct offering. Incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed with the SEC on August 13, 2009.

[Back to Table of Contents](#)

No.	Description
10.16	Employment Agreement, effective as of July 1, 2013, between Palatin and Carl Spana. * †
10.17	Employment Agreement, effective as of July 1, 2013, between Palatin and Stephen T. Wills. * †
10.18	Third Amendment dated September 24, 2009 to the Research Collaboration and License Agreement between Palatin and AstraZeneca AB. Incorporated by reference to Exhibit 10.1 of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, filed with the SEC on November 13, 2009. We have obtained confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
10.19	Underwriting Agreement dated February 24, 2011 by and between Palatin and Roth Capital Partners, LLC. Incorporated by reference to Exhibit 1.1 of our Current Report on Form 8-K, filed with the SEC on February 24, 2011.
10.20	2011 Stock Incentive Plan, as amended. * †
10.21	Form of Restricted Share Unit Agreement under the 2011 Stock Incentive Plan. Incorporated by reference to Exhibit 10.2 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on May 13, 2011. †
10.22	Form of Nonqualified Stock Option Agreement under the 2011 Stock Incentive Plan. Incorporated by reference to Exhibit 10.3 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on May 13, 2011. †
10.23	Form of Incentive Stock Option Agreement under the 2011 Stock Incentive Plan. Incorporated by reference to Exhibit 10.4 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on May 13, 2011. †
10.24	Letter agreement dated October 7, 2011 between Palatin and Biotechnology Value Fund, L.P. Incorporated by reference to Exhibit 10.01 of our Current Report on Form 8-K, filed with the SEC on October 7, 2011.
10.25	Purchase Agreement, dated July 2, 2012, by and between Palatin Technologies, Inc. and QVT Fund IV LP, QVT Fund V LP and Quintessence Fund L.P. Incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed with the SEC on July 6, 2012.
10.26	Registration Rights Agreement, dated July 2, 2012, by and between Palatin Technologies, Inc. and QVT Fund IV LP, QVT Fund V LP and Quintessence Fund L.P. Incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K, filed with the SEC on July 6, 2012.
21	Subsidiaries of the registrant. *
23	Consent of KPMG LLP. *
31.1	Certification of Chief Executive Officer. *
31.2	Certification of Chief Financial Officer. *

32.1	Certification of principal executive officer pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
32.2	Certification of principal financial officer pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
101.INS	XBRL Instance Document *
101.SCH	XBRL Taxonomy Extension Schema Document *
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document *
101.LAB	XBRL Taxonomy Extension Label Linkbase Document *
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document *
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document *

* Exhibit filed or furnished with this report.

† Management contract or compensatory plan or arrangement.

[Back to Table of Contents](#)

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

PALATIN TECHNOLOGIES, INC.

Date: September 27, 2013

By: /s/ Carl Spana
Carl Spana, Ph.D.
President and Chief Executive
Officer
(principal executive officer)

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

Signature	Title	Date
/s/ Carl Spana Carl Spana	President, Chief Executive Officer and Director (principal executive officer)	September 27, 2013
/s/ Stephen T. Wills Stephen T. Wills	Executive Vice President, Chief Financial Officer and Chief Operating Officer (principal financial and accounting officer)	September 27, 2013
/s/ John K.A. Prendergast John K.A. Prendergast	Chairman and Director	September 27, 2013
/s/ Perry B. Molinoff Perry B. Molinoff	Director	September 27, 2013
/s/ Robert K. deVeer, Jr. Robert K. deVeer, Jr.	Director	September 27, 2013
/s/ Zola P. Horovitz Zola P. Horovitz	Director	September 27, 2013
/s/ Robert I. Taber Robert I. Taber	Director	September 27, 2013
/s/ J. Stanley Hull J. Stanley Hull	Director	September 27, 2013
/s/ Alan W. Dunton Alan W. Dunton	Director	September 27, 2013
/s/ Angela Rossetti Angela Rossetti	Director	September 27, 2013

[Back to Table of Contents](#)

EXHIBIT INDEX

No.	Description
3.01	Restated certificate of incorporation, as amended. *
3.02	Bylaws. Incorporated by reference to Exhibit 3.1 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2007, filed with the SEC on February 8, 2008.
4.01	Form of warrant issued to purchasers in our August 2009 registered direct offering. Incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed with the SEC on August 13, 2009.
4.02	Warrant Agreement dated as of March 1, 2011, between Palatin and American Stock Transfer & Trust Company, a New York limited liability trust company. Incorporated by reference to Exhibit 4.1 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on May 13, 2011.
4.03	Definitive form of Series A 2011 Warrant certificate pursuant to Palatin's effective registration statement No. 333-170227 on Form S-1. Incorporated by reference to Exhibit 4.2 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on May 13, 2011.
4.04	Definitive form of Series B 2011 Warrant certificate pursuant to Palatin's effective registration statement No. 333-170227 on Form S-1. Incorporated by reference to Exhibit 4.3 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on May 13, 2011.
4.05	Definitive form of underwriters' warrant to purchase common stock pursuant to Palatin's effective registration statement No. 333-170227 on Form S-1. Incorporated by reference to Exhibit 4.4 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on May 13, 2011.
4.06	Warrant issued to Noble International Investments, Inc. at an exercise price of \$0.60 per share in connection with entering into a contract for financial advisory services. Incorporated by reference to Exhibit 4.1 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2011, filed with the SEC on February 14, 2012.
4.07	Form of warrant issued to Noble International Investments, Inc. at exercise prices of \$1.00 and \$1.50 per share in connection with entering into a contract for financial advisory services. Incorporated by reference to Exhibit 4.2 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2011, filed with the SEC on February 14, 2012.
4.08	Warrant issued to Chardan Capital Markets, LLC at an exercise price of \$0.75 per share in connection with entering into a contract for financial advisory services. Incorporated by reference to Exhibit 4.1 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, filed with the SEC on May 14, 2012.
4.09	Form of Series A 2012 common stock purchase warrant. Incorporated by reference to Exhibit 4.1 of our Current Report on Form 8-K, filed with the SEC on July 6, 2012.

[Back to Table of Contents](#)

No.	Description
4.10	Form of Series B 2012 common stock purchase warrant. Incorporated by reference to Exhibit 4.2 of our Current Report on Form 8-K, filed with the SEC on July 6, 2012.
10.01	1996 Stock Option Plan, as amended. Incorporated by reference to Exhibit 10.01 of our Annual Report on Form 10-K for the year ended June 30, 2009, filed with the SEC on September 28, 2009. †
10.02	Form of Option Certificate (incentive option) under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed with the SEC on September 21, 2005. †
10.03	Form of Incentive Stock Option Agreement under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K, filed with the SEC on September 21, 2005. †
10.04	Form of Option Certificate (non-qualified option) under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.3 of our Current Report on Form 8-K, filed with the SEC on September 21, 2005. †
10.05	Form of Non-Qualified Stock Option Agreement under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.4 of our Current Report on Form 8-K, filed with the SEC on September 21, 2005. †
10.06	Research Collaboration and License Agreement dated January 30, 2007, between Palatin and AstraZeneca AB. Incorporated by reference to Exhibit 10.2 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2006, filed with the SEC on February 8, 2007. We have obtained confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
10.07	Palatin Technologies, Inc. 2007 Change in Control Severance Plan. Incorporated by reference to Exhibit 10.4 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2007, filed with the SEC on February 8, 2008. †
10.08	2005 Stock Plan, as amended December 7, 2007, March 10, 2009 and May 13, 2009. Incorporated by reference to Exhibit 10.1 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2009, filed with the SEC on May 15, 2009. †
10.09	Form of Executive Officer Option Certificate. Incorporated by reference to Exhibit 10.1 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed with the SEC on May 14, 2008. †
10.10	Form of Amended Restricted Stock Unit Agreement. Incorporated by reference to Exhibit 10.2 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed with the SEC on May 14, 2008. †
10.11	Form of Amended Option Certificate (incentive option) under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.3 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed with the SEC on May 14, 2008. †
10.12	First Amendment dated June 27, 2008 to the Research Collaboration and License Agreement between Palatin and AstraZeneca AB. Incorporated by reference to Exhibit 10.28 of our Annual Report on Form 10-K for the year ended June 30, 2008, filed with the SEC on September 29, 2008. We have obtained confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the

information subject to the confidentiality request.

- 10.13 Second Amendment dated December 5, 2008 to the Research Collaboration and License Agreement between Palatin and AstraZeneca AB. Incorporated by reference to Exhibit 10.2 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2008, filed with the SEC on February 13, 2009. We have obtained confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
- 10.14 Clinical Trial Sponsored Research Agreement dated December 5, 2008 to the Research Collaboration and License Agreement between Palatin and AstraZeneca AB. Incorporated by reference to Exhibit 10.3 of our Quarterly Report on Form 10-Q for the quarter ended December 31, 2008, filed with the SEC on February 13, 2009. We have obtained confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
- 10.15 Form of securities purchase agreement for our August 2009 registered direct offering. Incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed with the SEC on August 13, 2009.

[Back to Table of Contents](#)

No.	Description
10.16	Employment Agreement, effective as of July 1, 2013, between Palatin and Carl Spana. * †
10.17	Employment Agreement, effective as of July 1, 2013, between Palatin and Stephen T. Wills. * †
10.18	Third Amendment dated September 24, 2009 to the Research Collaboration and License Agreement between Palatin and AstraZeneca AB. Incorporated by reference to Exhibit 10.1 of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2009, filed with the SEC on November 13, 2009. We have obtained confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
10.19	Underwriting Agreement dated February 24, 2011 by and between Palatin and Roth Capital Partners, LLC. Incorporated by reference to Exhibit 1.1 of our Current Report on Form 8-K, filed with the SEC on February 24, 2011.
10.20	2011 Stock Incentive Plan, as amended. * †
10.21	Form of Restricted Share Unit Agreement under the 2011 Stock Incentive Plan. Incorporated by reference to Exhibit 10.2 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on May 13, 2011. †
10.22	Form of Nonqualified Stock Option Agreement under the 2011 Stock Incentive Plan. Incorporated by reference to Exhibit 10.3 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on May 13, 2011. †
10.23	Form of Incentive Stock Option Agreement under the 2011 Stock Incentive Plan. Incorporated by reference to Exhibit 10.4 of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2011, filed with the SEC on May 13, 2011. †
10.24	Letter agreement dated October 7, 2011 between Palatin and Biotechnology Value Fund, L.P. Incorporated by reference to Exhibit 10.01 of our Current Report on Form 8-K, filed with the SEC on October 7, 2011.
10.25	Purchase Agreement, dated July 2, 2012, by and between Palatin Technologies, Inc. and QVT Fund IV LP, QVT Fund V LP and Quintessence Fund L.P. Incorporated by reference to Exhibit 10.1 of our Current Report on Form 8-K, filed with the SEC on July 6, 2012.
10.26	Registration Rights Agreement, dated July 2, 2012, by and between Palatin Technologies, Inc. and QVT Fund IV LP, QVT Fund V LP and Quintessence Fund L.P. Incorporated by reference to Exhibit 10.2 of our Current Report on Form 8-K, filed with the SEC on July 6, 2012.
21	Subsidiaries of the registrant. *
23	Consent of KPMG LLP. *
31.1	Certification of Chief Executive Officer. *
31.2	Certification of Chief Financial Officer. *

32.1	Certification of principal executive officer pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
32.2	Certification of principal financial officer pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
101.INS	XBRL Instance Document *
101.SCH	XBRL Taxonomy Extension Schema Document *
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document *
101.LAB	XBRL Taxonomy Extension Label Linkbase Document *
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document *
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document *

* Exhibit filed or furnished with this report.

† Management contract or compensatory plan or arrangement.