

# **SECURITIES & EXCHANGE COMMISSION EDGAR FILING**

# Palatin Technologies, Inc.

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

# **FORM 10 - K**

☑ ANNUAL REPORT PURSUANT TO SECT	ION 13 OR 15(d) OF THE SECUR	ITIES EXCHANGE ACT OF 1934
F	or the fiscal year ended June 30, 2	2014
	or	
☐ TRANSITION REPORT PURSUANT TO S	ECTION 13 OR 15(d) OF THE SEC	CURITIES EXCHANGE ACT OF 1934
For the tra	nsition period fromto	)
	Commission file number: 001-155	43
	ATIN TECHNOLOGIES name of registrant as specified in i	
Delaware		95-4078884
(State or other jurisdiction of incorporation or organization)		(I.R.S. Employer Identification No.)
4B Cedar Brook Drive Cranbury, New Jersey		08512
(Address of principal executive off	ices)	(Zip Code)
(Regist	(609) 495-2200 rant's telephone number, including	area code)
· ·		
Securities	registered pursuant to Section 12(	
Title of Each Class	N	lame of Each Exchange on Which Registered
Common Stock, par value \$.01 per	share	NYSE MKT
Securities re	gistered pursuant to Section 12(g) o	of the Act: None
Indicate by check mark if the registrant is a well-known	wn seasoned issuer, as defined in	Rule 405 of the Securities Act. Yes□ No ☑
Indicate by check mark if the registrant is not require	ed to file reports pursuant to Sectio	n 13 or Section 15(d) of the Act. Yes□ No ☑
- · · · · · · · · · · · · · · · · · · ·	or such shorter period that the reg	led by Section 13 or 15(d) of the Securities Exchange istrant was required to file such reports), and (2) has
Yes ☑ No □		
•	uant to Rule 405 of Regulation S-	ed on its corporate Web site, if any, every Interactive T during the preceding 12 months (or for such shorter
	•	egulation S-K is not contained herein, and will not be
contained, to the best of the registrant's knowledge Form 10-K or any amendment to this Form 10-K.	, in definitive proxy or information :	statements incorporated by reference in rait in or this
Form 10-K or any amendment to this Form 10-K.   Indicate by check mark whether the registrant is a	arge accelerated filer, an accelera	ted filer, a non-accelerated filer, or a smaller reporting ler reporting company" in Rule 12b-2 of the Exchange

Smaller reporting company  $\ensuremath{\square}$ 

Non-accelerated filer  $\square$ 

(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, 2013): \$28,101,335.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date (September 11, 2014): 39,490,161.

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#### 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) fillings.

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

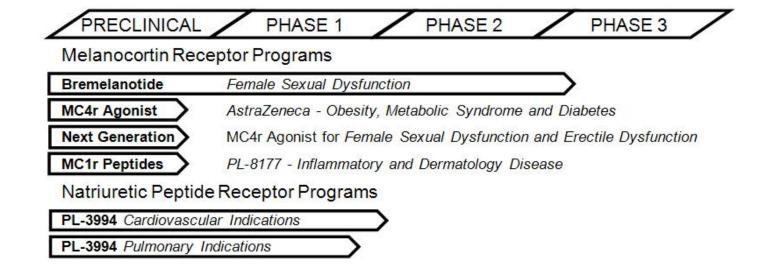
#### Overview

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, cardiovascular diseases, pulmonary 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 last quarter of calendar 2014.
- Use of 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 (MC1r) agonist peptides, for treatment of inflammatory and dermatologic disease indications.

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



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 third parties.

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 meetings with the U.S. Food and Drug Administration (FDA), and are preparing to start patient enrollment in the Phase 3 program in the fourth quarter of calendar 2014, but may curtail or delay clinical trial initiation unless we have adequate funds, or commitments for adequate funds, to complete Phase 3 clinical trials.

In August 2014, we entered into an agreement with Gedeon Richter Plc. (Gedeon Richter) to co-develop and commercialize bremelanotide for FSD in the European Union, other European countries and additional selected countries. Under this agreement we will contribute, with Gedeon Richter, to the costs of co-development activities for obtaining regulatory approval in Europe. Gedeon Richter will exclusively market bremelanotide for FSD in the licensed territory, and will be responsible for all sales, marketing and commercial activities, including associated costs, in the licensed territory.

We have received €7.5 million (\$9.8 million) in total upfront payments from Gedeon Richter, and will receive a milestone payment of €2.5 million (\$3.3 million) upon the initiation of our Phase 3 clinical trial program in the United States. We have the potential to receive up to €80 million (\$105.6 million) in regulatory and sales related milestones, and low double-digit royalties on net sales in the licensed territory. Our agreement remains in effect as long as Gedeon Richter is selling bremelanotide on which a royalty is owed. The agreement may be terminated by either party upon notice in the event of a material breach or insolvency. In the event Gedeon Richter terminates the agreement because we breached the agreement or are insolvent, Gedeon Richter's license will become fully paid-up, royalty free, perpetual and irrevocable. If Palatin fails to initiate its Phase 3 program by an agreed date, Gedeon Richter at its option may elect to terminate the license and receive a specified payment. In the event that we terminate the agreement because Gedeon Richter breached the agreement or is insolvent, upon timely request all regulatory approvals for bremelanotide in the licensed territory will be transferred to us or our designee.

Phase 2B Clinical Trial Results. 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 hypoactive sexual desire disorder, female sexual arousal disorder or both. 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 hypoactive sexual desire disorder, female sexual arousal disorder or both 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. Satisfying sexual events, overall sexual functioning and distress related to sexual dysfunction were measured using validated patient reported outcome measurement tools. Bremelanotide showed a statistically significant increase in the number of satisfying sexual events compared against placebo at both the 1.75 mg dose and pooled results of the 1.75 and 1.25 mg doses. The mean increase in satisfying sexual events at 1.75 mg dose levels was 0.8 satisfying sexual events per month, with a p value of 0.0215 against placebo. For the pooled doses, the mean increase in satisfying sexual events was 0.7 satisfying sexual events per month with a p value of 0.0180 against placebo.

The mean change from baseline in a validated measurement tool of overall sexual functioning, the Female Sexual Function Index (FSFI) total score, was 4.4 at the 1.75 mg dose level, with a p value of 0.002 against placebo. The mean change from baseline in a validated measurement tool of distress related to sexual dysfunction, the Female Sexual Distress Scale-Desire/Arousal/Orgasm (FSDS-DAO) total score, was -13.1 at the 1.75 mg dose level, with a p value of 0.013 against placebo.

A significantly higher percentage of women receiving the 1.75 mg bremelanotide dose, 55%, achieved a clinically important change from baseline of at least one satisfying sexual event compared to 37% of women receiving placebo. In addition, compared against placebo a significantly higher percentage of women also achieved a clinically important improvement in sexual function, as measured by the FSFI (56% vs. 23%), and a clinically important decrease in distress associated with sexual dysfunction as measured by the FSDS-DAO (69% vs. 45%).

Using a validated self-assessment questionnaire of treatment benefit, 79.5% of blinded patients receiving the 1.75 mg dose of bremelanotide reported they benefited from taking the drug, compared to 48.4% of blinded patients receiving placebo.

Bremelanotide was well-tolerated during the Phase 2B clinical 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, with less than 3% discontinuation due to an adverse event. No serious adverse events were attributable to bremelanotide during the trial.

Phase 3 Clinical Trial Plans. 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 and expect to submit protocols for the pivotal Phase 3 studies in the third quarter of calendar 2014, have manufactured drug product for clinical trial use and are in the process of negotiating 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 550 randomized patients with two arms, one a fixed bremelanotide dose and one placebo. Hypoactive sexual desire disorder is the single largest specific diagnosis in FSD. Patients in the parallel group trials will have the option, after completion of the trial, to continue in an open-label safety extension study. We will also conduct 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 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.

With Gedeon Richter we met with the European Medicines Agency and received regulatory advice on the Phase 3 clinical data required for approval of bremelanotide for FSD in the European Union. We anticipate that clinical studies will be conducted in Europe.

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 12% reporting distress associated with their symptoms associated with FSD.

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 autoinjector device which is expected to 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.

**Melanocortin Receptor-1 (MC1r) Peptide Agonists.** We have initiated preclinical studies with MC1r peptide drug candidates for a number of indications, primarily inflammatory disease-related indications. The MC1r is upregulated in a number of diseases, including inflammatory bowel disease, nephritis (inflammation of the kidneys), and rheumatoid arthritis, and ocular indications such as uveitis and dry eye. We believe that MC1r peptides have an anti-inflammatory effect and are involved in regulation of the immune system. MC1r peptides also have

Our MC1r peptide drug candidates are highly specific, with substantially greater binding and efficacy at MC1r than at other melanocortin receptors. In vitro safety studies have shown that our MC1r peptide drug candidates have no activity in a wide range of various receptors, ion channels and kinases. We have selected one of our MC1r peptide drug candidates, designated PL-8177, as a clinical trial candidate.

Animal studies that we have conducted with our MC1r peptide drug candidates have shown positive results in experimental models of inflammatory bowel disease, uveitis and nephritis. We are continuing to conduct studies on a number of different indications. We have completed preclinical toxicology testing on PL-8177 and are completing final reports, and anticipate filing an Investigational New Drug (IND) application on PL-8177 as early as the fourth quarter of calendar 2014. Contingent on adequate available funds, we anticipate conducting a first-in-man Phase 1 clinical trial in the first half of calendar 2015.

**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 effectiveness in obesity and related metabolic signals, 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 activation, including FSD, ED and obesity. 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 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.

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 that 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 that we granted under the agreement become permanent, with financial terms, including royalties, to be determined by arbitration.

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

**Other Melanocortin Programs.** We 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 heart failure, acute asthma, other pulmonary diseases 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 heart failure, acute exacerbations of asthma 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 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.

Patient populations have been identified which have reduced levels of endogenous active natriuretic peptides, including endogenous active ANP. The reduced levels have a variety of causes, including mutations in endogenous natriuretic peptides and in enzymes necessary to convert natriuretic peptide sequences to their active form. Patients with reduced levels of endogenous active natriuretic peptides are reported to have a poor response to current drug therapies and to have increased rates of cardiac remodeling and cardiac events.

We have planned a repeat dose Phase 2 clinical trial in patients with heart failure to evaluate safety profiles as well as pharmacokinetic (period to metabolize or excrete the drug) and pharmacodynamic (period of action or effect of the drug) endpoints. Patient populations would include patients diagnosed with heart failure, including patients with reduced levels of endogenous active natriuretic peptides. Contingent on adequate available funds, we intend to initiate this trial in the first half of calendar 2015. Assuming favorable results from this trial, we have planned a repeat dose Phase 2 proof-of-principle clinical trial in patients with heart failure, which would involve treatment for a three to six month period, and would evaluate cardiac function, effects on remodeling, symptom improvement and hospitalization admission rates. This trial will be initiated following completion of the first repeat dose Phase 2 clinical trial.

*PL-3994 for Acute Exacerbations of Asthma.* Research over the past two decades has demonstrated potent bronchodilator effects with both systemic and inhalation administration of natriuretic peptides. NPR-A agonism is known to relax smooth muscles in airways and works through a pathway independent of the beta-2 adrenergic receptor. Preclinical testing demonstrated potent airway smooth muscle relaxation in guinea pig and human tissues using PL-3994, and animal studies in sensitized guinea pigs have demonstrated a bronchodilator effect with PL-3994 using both subcutaneous and inhalation administration.

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

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

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

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.

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 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. For asthma indications we believe that inhalation administration of PL-3994 may be preferable to subcutaneous or other systemic administration.

### **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 heart failure, acute exacerbations of asthma and refractory hypertension.

Some compound series have been derived using our proprietary and patented platform technology, called MIDAS<sup>TM</sup> 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 \$10.8 million for the fiscal year ended June 30, 2014 (fiscal 2014), \$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).

### Competition

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

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

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

Bremelanotide for Treatment of Female Sexual Dysfunction. There is competition and financial incentive to develop, market and sell drugs for the treatment of FSD, for which there is no approved drug in the United States. We are aware of several drugs at various stages of development, most of 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. While the FDA did not approve the drug for marketing, a third party has acquired the drug, and announced that it will resubmit an NDA to the FDA by the third quarter of calendar 2014. 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. There are other companies reported to be developing new drugs for FSD indications, some of which may be in clinical trials in the United States or elsewhere. We are not aware of any company actively developing a melanocortin receptor agonist drug for FSD.

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. Novartis AG has reported clinical trial results with a combination drug, LCZ696, which inhibits both the angiotensin II receptor and neprilysin (an enzyme which inactivates endogenous active natriuretic peptides). LZC696 results in increases of endogenous active ANP levels, and thus has a mechanism of action with similarities to PL-3994. 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.

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.

MC4r Peptides for Erectile Dysfunction. Leading drugs approved for ED indications are PDE-5 inhibitors which target the vascular system, such as sildenafil (sold under the trade name Viagra®), vardenafil (sold under the trade name Levitra®) and tadalafil (sold under the trade name Cialis®). Other drugs approved for ED indications include alprostadil for injection (sold under the trade name Caverject Impulse® among others), which is injected directly into the penis, and alprostadil in urethral suppository format (sold under the trade name MUSE®). In addition, a variety of devices, including vacuum devices and surgical penile implants, have been approved for ED indications. We are aware of a number of companies developing new drugs for ED indications, some of which are in clinical trials in the United States and elsewhere. We are not aware of any company actively developing a melanocortin receptor agonist drug for ED.

Obesity. There are a number of 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. At least one Phase 2 study has been reported on use of an MC4r agonist for obesity indications.

MC1r Peptides for Dermatologic and Inflammatory Disease-Related Indications. Many dermatologic and inflammatory disease-related indications are treated using systemic steroids or immunosuppressant drugs, both of which have side effects which can be dose limiting. There are a large number of approved biological drugs and biological drugs under development for treatment of dermatologic and inflammatory disease-related indications.

# **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 Australia, Austria, Belgium, Brazil, Canada, Cyprus, Denmark, Finland, France, Germany, Greece, Hong Kong, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, Monaco, Netherlands, New Zealand, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. 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 a patent application pending in the United States and the World Intellectual Property Organization pursuant to the Patent Cooperation Treaty on methods for treating female sexual dysfunction with bremelanotide. We will be required to enter national stage prosecution on this application, including filing the application in countries we select, by May 2015. If any patent issues in the United States, the presumptive term will be until 2033. Whether we will be able to obtain a patent term extension under the Hatch-Waxman Amendments, assuming that a method of treatment patent issues in the United States, 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.

We own two issued patents in the United States, Australia, China, Eurasian patent office (for the Russia Federation), 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 Brazil, Canada, India, Israel, Japan, Korea, Mexico, and South Africa and before the European patent office. The presumptive term of the patent issued in the United States is until 2029. We also own an issued patent in South Africa and have pending patent applications for a second class of alternative melanocortin receptor-specific peptides for treatment of sexual dysfunction in the United States, Australia, Brazil, Canada, China, India, Israel, Japan, Korea, Mexico, New Zealand 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 issued United States and South African patents 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 New Zealand 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 on the PL-3994 substance and other natriuretic peptide receptor agonist compounds have issued in Australia, Austria, Belgium, China, Colombia, Denmark, Finland, France, Germany, Hong Kong, Hungary, India, Ireland, Israel, Italy, Japan, Mexico, Netherlands, Philippines, Eurasian patent office (for the Russian Federation), South Africa, Spain, Sweden and Switzerland. Patent applications on the PL-3994 substance and other natriuretic peptide receptor agonist compounds are pending in Brazil, Canada, Israel and Korea. Applications claiming precursor molecules for the PL-3994 substance and other compounds have issued in the United States, Australia, France, Germany, India, Ireland, Japan, Mexico, Netherlands, Philippines, Korea, South Africa, Sweden, Switzerland and the United Kingdom. Patent applications on the precursor molecules are pending in Brazil, Canada, China, Hong Kong, Israel and before the Eurasian Patent Office. We also own an issued United States patent claiming use of the PL-3994 substance for treatment of acute asthma and chronic obstructive pulmonary disease, which has a term until 2031. 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. 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-nine 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.

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

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

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

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

### **Governmental Regulation**

The FDA, comparable agencies in other countries and state regulatory authorities have established regulations and guidelines which apply to, among other things, the clinical testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising, promotion, marketing and distribution of our proposed products. Noncompliance with applicable requirements can result in fines, recalls or seizures of products, total or partial suspension of production, refusal of the regulatory authorities to approve marketing applications, withdrawal of approvals and criminal prosecution.

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

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

In addition to obtaining approval of 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.

Our PL-3994 product candidate is a peptide mimetic molecule, incorporating a proprietary amino acid mimetic structure and amino acids. We identified a manufacturer which made the product in quantities sufficient for Phase 1 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.

Our MC1r and MC4r agonist product candidates are synthetic peptides, which we have manufactured only at laboratory scale. 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 11, 2014, we employed 17 persons full time, of whom 11 are engaged in research and development activities and 6 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

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, 2014, we had an accumulated deficit of \$274.0 million. We expect to incur additional losses as we continue our development of bremelanotide, PL-3994 and other product candidates. Unless and until we receive approval from the FDA or other equivalent regulatory authorities outside the United States, we cannot sell our products and will not have product revenues from them. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from 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, 2014, we had cash and cash equivalents of \$12.2 million, with current liabilities of \$1.8 million net of unearned revenues of \$1.0 million. In September 2014 we received \$8.8 million pursuant to our agreement with Gedeon Richter. We believe we have sufficient currently available working capital to fund our planned operations through the quarter ending September 30, 2015, not including initiation of our pivotal Phase 3 clinical trials for bremelanotide for FSD or other planned clinical trials. 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.

We are preparing to initiate Phase 3 clinical trials of bremelanotide for FSD, and intend to start patient enrollment in the Phase 3 program in the fourth quarter of calendar 2014, but may curtail or delay clinical trial initiation unless we have adequate funds, or commitments for adequate funds, to complete Phase 3 clinical trials. We estimate that the Phase 3 program, including regulatory filings for product approval, will cost at least \$80.0 million. We are seeking funds to support the Phase 3 program through collaborative arrangements on bremelanotide in addition to our agreement with Gedeon Richter, 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 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.

# 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 that 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 filling for regulatory approval of our product candidates. Additional factors that can cause delay or termination of our human clinical trials include:

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

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

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

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

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

- completion of non-clinical tests including preclinical laboratory and formulation studies and animal testing and toxicology;
- submission to the FDA of an IND application, which must become effective before clinical trials may begin;
- performance of adequate and well-controlled Phase 1, 2 and 3 human clinical trials to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of an NDA;
- FDA review and approval of the NDA before any commercial marketing or sale; and
- compliance with post-approval commitments and requirements.

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

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

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

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

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

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

- perceptions by members of the healthcare community, including physicians, about its safety and effectiveness;
- cost-effectiveness relative to competing products and technologies;
- availability of reimbursement for our products from third party payors such as health insurers, health maintenance organizations and government programs such as Medicare and Medicaid; and
- advantages over alternative treatment methods.

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

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

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

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

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

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

We do not have the facilities to manufacture bremelanotide, PL-3994, PL-8177, other melanocortin receptor agonist compounds or our other potential products. Our contract manufacturers must perform these manufacturing activities in a manner that complies with FDA regulations. Our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection. The manufacturers of approved products and their manufacturing facilities will be subject to continual review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing regulatory requirements, including the FDA's GMPs regulations. Failure of third-party manufacturers to comply with GMPs or other FDA requirements may result in enforcement action by the FDA. Failure to conduct their activities in compliance with FDA regulations could delay our development programs or negatively impact our ability to receive FDA approval of our potential products or continue marketing if they are approved. Establishing relationships with new suppliers, who must be FDA-approved, is a time-consuming and costly process.

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

We are developing bremelanotide for FSD, 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 heart failure, asthma 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 license, co-development and commercialization agreement with Gedeon Richter for bremelanotide for FSD in a licensed territory, we have limited control over development activities, including regulatory approvals, and no direct control over commercialization efforts. Gedeon Richter may abandon further development of bremelanotide in its licensed territory, including terminating the agreement, for any reason, including a change of priorities within Gedeon Richter or lack of success in clinical trials necessary for obtaining regulatory approvals. Because the potential value of the license arrangement with Gedeon Richter is contingent upon the successful development and commercialization of bremelanotide for FSD in the licensed territory, the ultimate value of this license will depend on the efforts of Gedeon Richter. If Gedeon Richter does not succeed in obtaining regulatory approval of bremelanotide for FSD in the licensed territory for any reason, or does not succeed in securing market acceptance of bremelanotide for FSD in the territory, or elects for any reason to discontinue development of bremelanotide for FSD, we may be unable to realize the potential value of this arrangement.

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 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.

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

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

#### Competing products and technologies may make our proposed products noncompetitive.

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

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

There are 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 a number of products approved for use in treating inflammatory diseases and dermatologic indication, and other products being developed, including products in clinical trials.

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, including a combination drug which increases endogenous active ANP levels.

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.

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.

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

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings, which may be costly whether we win or lose, and which could result in a substantial diversion of our management resources.

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

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

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

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

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

We rely on our relatively small management team and staff as well as various contractors and consultants to provide critical services. Our ability to execute our bremelanotide, PL-3994 and MC1r peptide clinical programs, and our preclinical programs on MC1r and MC4r peptide drug candidates, 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.

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. We will require significant additional resources and capital 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.

### Risks Relating to Owning Our Common Stock

As of September 11, 2014, there were 96,380,178 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 11, 2014, 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;
- 4,229,913 shares issuable on the exercise of stock options, at exercise prices ranging from \$0.60 to \$37.50 per share;
- 845,900 shares issuable under restricted stock units which vest on dates between June 25, 2015 and June 25, 2018, subject to the fulfillment of service conditions; and
- 91,251,531 shares issuable on the exercise of warrants at exercise prices ranging from \$0.01 to \$1.50 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

For the 12 month period ended August 31, 2014, the price of our stock has been volatile, ranging from a high of \$1.50 per share to a low of \$0.56 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 11, 2014, 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 June 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.

### 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, 2012.

FISCAL YEAR ENDED JUNE 30, 2014	HIGH	LOW
Fourth Quarter	\$ 1.43	\$ 0.97
Third Quarter	1.50	0.73
Second Quarter	0.83	0.56
First Quarter	0.76	0.59
FISCAL YEAR ENDED JUNE 30, 2013	нідн	LOW
Fourth Quarter	\$ 0.79	\$ 0.51
Third Quarter	0.71	0.54
Second Quarter	1.10	0.53

1.20

0.45

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

Holders of common stock On September 11, 2014, we had approximately 94 record holders of common stock and the closing sales price of our common stock as reported on the NYSE MKT was \$0.95 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 92,560 shares were withheld during the quarter ended June 30, 2014 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:

Total Number of Shares Purchased (1)			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	
8,930	\$	1.25	-	-	
-		-	-	-	
83,630		1.00	-	-	
92,560	\$	1.02			
	of Shares Purchased (1) 8,930 - 83,630	of Shares Average Paid pe 8,930 \$ \$ 83,630	of Shares         Average Price Paid per Share           8,930         \$ 1.25           83,630         1.00	Total Number of Shares Purchased (1)  8,930  83,630  Average Price Paid per Share  Paid per Share  1.25  Shares Purchased as Part of Publicly Announced Plans or Programs	

(1) Consists solely of 92,560 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 11, 2014, 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.

FIGURE VEAD ENDED HINE OF ONE

First Quarter

Not applicable.

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

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

### **Critical Accounting Policies.**

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

# Revenue Recognition

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

### 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, 2014 Compared to the Year Ended June 30, 2013:

Revenue – For the fiscal year ended June 30, 2014 (fiscal 2014), we recognized no revenue, compared to \$10,000 for the fiscal year ended June 30, 2013 (fiscal 2013), pursuant to our license agreement with AstraZeneca. Revenue consisted entirely of reimbursement of development costs and per-employee compensation, earned at the contractual rate.

Research and Development – Research and development expenses were \$10.8 million for fiscal 2014 compared to \$10.5 million for fiscal 2013. Research and development expenses related to our bremelanotide, PL-3994, peptide melanocortin agonist, obesity and other preclinical programs were \$7.9 million and \$7.6 million in fiscal years 2014 and 2013, respectively. The spending was primarily related to the preparation costs of our Phase 3 studies of bremelanotide for the treatment of FSD and secondarily to costs related to our other preclinical and development programs. 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 were \$2.9 million for fiscal 2014 and fiscal 2013, respectively.

Cumulative spending from inception to June 30, 2014 on our bremelanotide, NeutroSpec (a previously marketed imaging product which has been terminated) and other programs (which includes PL-3994, PL-8177, other melanocortin receptor agonists, obesity and other discovery programs) amounts to approximately \$170.9 million, \$55.6 million and \$64.5 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

General and Administrative – General and administrative expenses were \$5.0 million for fiscal 2014 compared to \$5.1 million for fiscal 2013. These expenses mainly consist of compensation and related costs.

Other Income (Expense) – Other income (expense) was \$13,000 and \$(7.0) million for fiscal 2014 and fiscal 2013, respectively. For fiscal 2014, we recognized \$19,000 of investment income compared to \$43,000 of investment income for fiscal 2013. Fiscal 2013 included the recognition of a \$7.0 million non-cash charge for the increase in the fair value of warrants related to the July 3, 2012 private placement offering.

Income Tax Benefit – Income tax benefits of \$1.8 million in fiscal 2014 and fiscal 2013, respectively, 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, 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.

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 was primarily the result of costs relating to our Phase 2B clinical trial evaluating the efficacy and safety of bremelanotide for the treatment of FSD.

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. 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 was the result of closing our research laboratory operations in connection with the lease expiration of our laboratory facilities in July 2012.

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 consisted 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 was 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 related 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 or successfully perform under 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 2014, we used \$12.2 million of cash for our operating activities, compared to \$13.6 million used in fiscal 2013 and \$15.5 million used in fiscal 2012. Lower net cash outflows from operations in fiscal 2014 compared to fiscal 2013 were primarily the result of the receipt of a \$1.0 million, non-refundable option fee, relating to a license, co-development and commercialization agreement with Gedeon Richter on bremelanotide for the treatment of FSD in Europe and selected other countries. 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. Our periodic accounts receivable balances will continue to be highly dependent on the timing of receipts from collaboration partners and the division of development responsibilities between us and our collaboration partners.

During fiscal 2014, net cash provided by investing activities was \$5.2 million, which consisted of \$5.2 million of proceeds from the maturity of short-term investments offset by \$6,000 used for capital expenditures. 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 and \$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 2014, cash used in financing activities of \$19,000 consisted of the payment of withholding taxes related to restricted stock units of \$36,000 and payments on capital lease obligation of \$20,000 offset by \$37,500 of proceeds from the exercise of common stock warrants. 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.

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, 2014, our cash and cash equivalents were \$12.2 million and our current liabilities were \$1.8 million, net of unearned revenue of \$1.0 million. In September 2014 we received \$8.8 million pursuant to our license, co-development and commercialization agreement with Gedeon Richter on bremelanotide for FSD in Europe and selected countries.

We intend to utilize existing capital resources, including approximately \$8.8 million received on execution of our agreement with Gedeon Richter, 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, including regulatory filings for product approval, will cost at least \$80.0 million. We are preparing to start patient enrollment in the bremelanotide Phase 3 program in the fourth quarter of calendar 2014, but may curtail or delay clinical trial initiation unless we have adequate funds, or commitments for adequate funds, to complete Phase 3 clinical trials. We intend to seek additional capital to support the Phase 3 program through collaborative arrangements on bremelanotide in addition to our agreement with Gedeon Richter, public or private equity or debt financings, or other sources.

We believe that our existing capital resources, together with approximately \$8.8 million received on execution of our agreement with

Gedeon Richter, will be adequate to fund our planned operations through the quarter ending September 30, 2015, not including initiation of our pivotal Phase 3 clinical trials for bremelanotide for FSD or other planned clinical trials. 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 bremelanotide for FSD or any of our other product candidates.

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, 2014:

Payments due by Period									
Total Less than 1 Year			1 - 3 Years		3 - 5 Years		More than 5 Years		
\$	236,355	\$	236,335	\$	-	\$	-	\$	-

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

Not applicable.

## Item 8. Financial Statements and Supplementary Data.

# Table of Contents Consolidated Financial Statements

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

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## 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, 2014 and 2013, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended June 30, 2014. 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, 2014 and 2013, and the results of their operations and their cash flows for each of the years in the three-year period ended June 30, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ KPMG LLP

Philadelphia, Pennsylvania

September 12, 2014

# PALATIN TECHNOLOGIES, INC.

# and Subsidiary Consolidated Balance Sheets

	June 30, 2014	June 30, 2013
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,184,605	
Short-term investments	-	5,249,654
Prepaid expenses and other current assets	156,393	332,267
Total current assets	12,340,998	24,749,553
Property and equipment, net	160,748	266,415
Other assets	57,308	58,131
Total assets	\$ 12,559,054	\$ 25,074,099
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 261,280	\$ 338,726
Accrued expenses	1,508,958	1,701,727
Capital lease obligations	-	19,909
Unearned revenue	1,000,000	-
Total current liabilities	2,770,238	2,060,362
Deferred rent	-	35,460
Total liabilities	2,770,238	2,095,822
Commitments and contengencies (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, 2014 and 2013,		
respectively	47	47
Common stock of \$0.01 par value – authorized 300,000,000 shares;		
issued and outstanding 39,416,595 shares as of June 30, 2014 and 39,116,948 as of June 30,		
2013, respectively	394,166	391,169
Additional paid-in capital	283,428,356	282,692,520
Accumulated deficit	(274,033,753)	(260,105,459)
Total stockholders' equity	9,788,816	22,978,277
Total liabilities and stockholders' equity	\$ 12,559,054	\$ 25,074,099

## PALATIN TECHNOLOGIES, INC. and Subsidiary Consolidated Statements of Operations

	Year Ended June 30,				
	2014	2013	2012		
REVENUES:					
License and contract	\$ -	\$ 10,361	\$ 73,736		
OPERATING EXPENSES:					
Research and development	10,826,921	10,528,691	13,813,376		
General and administrative	4,960,731	5,066,830	5,045,741		
Total operating expenses	15,787,652	15,595,521	18,859,117		
Loss from operations	(15,787,652)	(15,585,160)	(18,785,381)		
OTHER INCOME (EXPENSE):					
Investment income	18,923	42,734	32,133		
Interest expense	(6,211)	(8,411)	(10,411)		
Increase in fair value of warrants	-	(7,069,165)	-		
Gain on disposition of supplies and equipment	-	4,620	442,248		
Total other income (expense), net	12,712	(7,030,222)	463,970		
Loss before income taxes	(15,774,940)	(22,615,382)	(18,321,411)		
Income tax benefit	1,846,646	1,753,208	1,068,233		
NET LOSS	\$ (13,928,294)	\$ (20,862,174)	\$ (17,253,178)		
Basic and diluted net loss per common share	\$ (0.13)	\$ (0.21)	\$ (0.49)		
Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share	106,679,476	97,618,714	34,900,591		

# PALATIN TECHNOLOGIES, INC.

## and Subsidiary

## Consolidated Statements of Stockholders' Equity

	Preferr	ed St	ock	Common Stock			Additional Paid-in	Accumulated	
_	Shares		Amount	Shares		Amount	Capital	Deficit	Total
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, net of costs	-		-	3,873,000		38,730	17,403,075	-	17,441,805
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
Stock-based									
compensation	-		-	378,750		3,788	817,552	-	821,340
Warrant exercises	-		-	50,000		500	37,000	-	37,500
Taxes withheld									
related to									
restricted stock units	-		-	(129,103)		(1,291)	(118,716)	-	(120,007)
Net loss			_					(13,928,294)	(13,928,294)
Balance, June 30,									
2014	4,697	\$	47	39,416,595	\$	394,166	\$283,428,356	\$(274,033,753)	\$ 9,788,816

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

	Year Ended June 30,					
	2014	2013	2012			
CASH FLOWS FROM OPERATING ACTIVITIES:						
Net loss	\$ (13,928,294)	\$ (20,862,174)	\$ (17,253,178			
Adjustments to reconcile net loss to net cash						
used in operating activities:						
Depreciation and amortization	111,906	111,844	949,542			
Accrued interest and amortization on premium/discount	-	(1,365)	-			
Gain on disposition of supplies and equipment	-	(4,620)	(442,248			
Stock-based compensation	821,340	625,031	892,301			
Increase in fair value of warrants	-	7,069,165	-			
Changes in operating assets and liabilities:						
Accounts receivable	-	27,631	103,518			
Prepaid expenses and other assets	176,697	816,605	(340,268			
Accounts payable	(77,446)	43,832	(202,014			
Accrued expenses and deferred rent	(311,859)	(1,475,319)	851,550			
Unearned revenue	1,000,000	-	(46,105			
Net cash used in operating activities	(12,207,656)	(13,649,370)	(15,486,902			
CASH FLOWS FROM INVESTING ACTIVITIES:						
Proceeds from sale/maturity of investments	5,249,654	750,000	_			
Proceeds from sale of supplies and equipment	5,243,054	4,620	494,384			
Purchases of property and equipment	(6,239)	(59,607)	(15,000			
Purchases of investments	(0,200)	(5,998,289)	(10,000			
	5,243,415		470.294			
Net cash provided by (used in) investing activities	5,245,415	(5,303,276)	479,384			
CASH FLOWS FROM FINANCING ACTIVITIES:						
Payments on capital lease obligations	(19,909)	(22,277)	(34,923			
Payment of withholding taxes related to restricted						
stock units	(36,377)	(87,411)				
Proceeds from exercise of common stock warrants and						
sale of common stock units	37,500	34,402,768	-			
Net cash (used in) provided by financing activities	(18,786)	34,293,080	(34,923			
NET (DECREASE) INCREASE IN CASH						
AND CASH EQUIVALENTS	(6,983,027)	15,340,434	(15,042,441			
CASH AND CASH EQUIVALENTS, beginning of year	19,167,632	3,827,198	18,869,639			
S. C. T. W. D. G. T. L. G. T. G. Sognilling of your	10,107,002	0,027,100	10,000,000			
CASH AND CASH EQUIVALENTS, end of year	\$ 12,184,605	\$ 19,167,632	\$ 3,827,198			
SUPPLEMENTAL CASH FLOW INFORMATION:						
Cash paid for interest	\$ 6,211	\$ 8,411	\$ 9,984			

#### **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 cardiovascular diseases, pulmonary diseases, obesity, erectile dysfunction, inflammatory diseases and dermatologic diseases. The Company has a license, co-development and commercialization agreement with Gedeon Richter Plc. (Gedeon Richter) to commercialize bremelanotide for FSD in Europe and selected countries, and 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 third parties.

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, 2014 of \$274.0 million and incurred a net loss for fiscal 2014 of \$13.9 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, 2014, the Company's cash and cash equivalents were \$12.2 million. In September 2014 the Company received \$8.8 million pursuant to its license, co-development and commercialization agreement with Gedeon Richter on bremelanotide for FSD in Europe and selected countries. 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, including regulatory filings for product approval, will cost at least \$80.0 million. The Company is preparing to initiate patient enrollment in the Phase 3 program in the fourth quarter of calendar 2014, but may curtail or delay clinical trial initiation unless we have adequate funds, or commitments for adequate funds, to complete Phase 3 clinical trials. The Company intends to seek additional capital to support the Phase 3 program through collaborative arrangements on bremelanotide, in addition to the Company's agreement with Gedeon Richter, public or private equity or debt financings, or other sources.

Management believes that the Company's existing capital resources, including \$8.8 million paid by Gedeon Richter pursuant to the agreement on bremelanotide for FSD, will be adequate to fund its planned operations through the quarter ending September 30, 2015, not including initiation of our pivotal Phase 3 clinical trials for bremelanotide for FSD or other planned clinical trials. 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.

#### **Notes to Consolidated Financial Statements**

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 and cash equivalents. The Company's cash and cash equivalents are primarily invested in one money market fund sponsored by a large financial institution. In the two-year period ended June 30, 2013, all license and contract revenues were from AstraZeneca.

#### (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 \$9,495,656 and \$16,284,184 in a money market fund at June 30, 2014 and 2013, 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 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.

#### **Notes to Consolidated Financial Statements**

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.

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, 2014, 2013 and 2012, the Company sold New Jersey state net operating loss carryforwards, which resulted in the recognition of \$1,846,646, \$1,753,208, and \$1,068,233, 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 9). 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.

#### **Notes to Consolidated Financial Statements**

As of June 30, 2014, 2013 and 2012, there were 29,358,926, 29,136,527, and 27,179,180 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 May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers," which requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. The ASU will replace most existing revenue recognition guidance in U.S. GAAP when it becomes effective. The new standard is effective for the Company on July 1, 2017. Early application is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company is evaluating the effect that ASU 2014-09 will have on its consolidated financial statements and related disclosures. The Company has not yet determined the effect of the standard on its ongoing financial reporting.

## (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 and \$73,736, respectively, as revenue in the years ended June 30, 2013 and 2012 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.

### **Notes to Consolidated Financial Statements**

AstraZeneca 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.

### (5) FAIR VALUE MEASUREMENTS

The fair value of cash equivalents and short-term investments is 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.

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, 2014:				
Money Market Fund	\$ 9,495,656	\$ 9,495,656	\$ -	\$ -
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	\$ -	\$ -

### (6) PROPERTY AND EQUIPMENT, NET

Property and equipment, net, consists of the following:

	June 30, 2014	June 30, 2013
Office equipment	\$ 1,180,210	\$ 1,180,210
Laboratory equipment	317,608	311,369
Leasehold improvements	751,226	751,226
	 2,249,044	2,242,805
Less: Accumulated depreciation and amortization	(2,088,296)	(1,976,390)
	\$ 160,748	\$ 266,415

The aggregate cost of assets acquired under capital leases was \$66,115 as of June 30, 2014 and June 30, 2013, respectively. Accumulated amortization associated with assets acquired under capital leases was \$40,771 as of June 30, 2014 and \$27,548 as of June 30, 2013.

#### **Notes to Consolidated Financial Statements**

#### (7) ACCRUED EXPENSES

Accrued expenses consist of the following:

	June 30,		June 30,
	2014		2013
Clinical study costs	\$ 617,055	\$	1,054,270
Other research related expenses	463,695		186,241
Professional services	211,711		208,731
Insurance premiums payable	-		125,671
Other	216,497		126,814
	\$ 1,508,958	\$	1,701,727

### (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 lease, which expires in June 2015. The remaining lease payments under this lease total \$236,335. The Company has started the process of reviewing its lease renewal options.

For the years ended June 30, 2014, 2013 and 2012, rent expense was \$219,686, \$372,754, and \$915,469, respectively.

Capital Leases – The Company has acquired certain of its equipment under leases classified as capital leases. The remaining capital lease was paid in full during fiscal year 2014.

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, 2014, 2013 and 2012, Company contributions were \$140,870, \$150,256, and \$124,351, 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.

#### **Notes to Consolidated Financial Statements**

## (9) STOCKHOLDERS' EQUITY

Series A Convertible Preferred Stock – As of June 30, 2014, 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, 2014, 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, 2014. 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 warrants). 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.

#### **Notes to Consolidated Financial Statements**

Outstanding Stock Purchase Warrants – As of June 30, 2014, the Company had outstanding warrants exercisable for shares of common stock as follows:

Shares of Common Stock	Exercise Price per Share	Latest Termination Date
331,969	3.30	August 17, 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
91,583,500		

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 year ended June 30, 2012, the Company recorded stock-based compensation related to these warrants of \$26,000.

In January 2014, the Company received \$37,500 and issued 50,000 shares of common stock pursuant to the exercise of warrants at an exercise price of \$0.75 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, 2014, 1,929,056 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.

#### **Notes to Consolidated Financial Statements**

The following table summarizes option activity for the years ended June 30, 2014, 2013 and 2012:

	20	2014			2013				2012			
		١	Veighted		١	Weighted		٧	Veighted			
	Number of		Average	Number of		Average	Number of		Average			
	Shares	Exe	ercise Price	Shares	Exe	ercise Price	Shares	Exe	ercise Price			
Outstanding at												
beginning of year	3,851,448	\$	1.99	2,181,853	\$	3.50	2,231,898	\$	4.05			
Granted	603,400		1.02	1,807,300		0.65	75,000		0.65			
Forfeited	(161,900)		0.68	(74,985)		5.20	(90,870)		3.64			
Expired	(50,975)		24.95	(62,720)		11.91	(34,175)		33.07			
Outstanding at												
end of year	4,241,973		1.63	3,851,448		1.99	2,181,853		3.50			
Exercisable at												
end of year	2,507,573		2.19	1,673,973		3.64	1,323,965		5.10			
Weighted average												
grant-date fair												
value of options												
granted during												
the year		\$	0.80		\$	0.56		\$	0.47			

The following table summarizes options outstanding as of June 30, 2014:

Number of Shares		Average	Weighted Average Remaining Term in Years	Aggregate Intrinsic Value	
·				'	
4,241,973	\$	1.63	7.7	\$	694,711
2,507,573	\$	2.19	6.8	\$	373,709
1,504,254	\$	0.80	8.8	\$	294,435
	Shares 4,241,973 2,507,573	Number of Shares Exe 4,241,973 \$ 2,507,573 \$	Shares         Exercise Price           4,241,973         \$ 1.63           2,507,573         \$ 2.19	Number of SharesWeighted Average Exercise PriceAverage Remaining Term in Years4,241,973\$ 1.637.72,507,573\$ 2.196.8	Number of Shares         Weighted Average Exercise Price         Average Remaining Term in Years         Introduction           4,241,973         \$ 1.63         7.7         \$           2,507,573         \$ 2.19         6.8         \$

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, 2014, the Company's weighted average assumptions for expected volatility, dividends, term and risk-free interest rate were 97.1%, 0%, 6.1 years and 1.9%, respectively. 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. 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, 2014, 2013 and 2012 the Company recorded stock-based compensation related to stock options of \$520,855, \$379,264 and \$533,445, respectively. As of June 30, 2014, there was \$910,028 of unrecognized compensation cost related to unvested options, which is expected to be recognized over a weighted-average period of 2.61 years.

#### **Notes to Consolidated Financial Statements**

In June 2014, the Company granted 325,000 options to its executive officers, 143,400 options to its employees and 135,000 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 \$265,726, \$117,247 and \$97,530, respectively, over the vesting period.

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 is amortizing the fair value of these options of \$287,000, \$204,000 and \$148,000, respectively, over the vesting period.

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 vesting period.

Stock options granted to the Company's executive officers and employees vest over a 48 month period, while stock options granted to its non-employee directors vest over a 12 month period.

During the year ended June 30, 2014, the Company made the following modifications to certain stock options that were granted to certain terminated employees in recognition of their prior services; i) accelerated the vesting, and ii) extended the date to exercise vested stock options to 24 months from the date of termination. An incremental \$22,000 of stock-based compensation expense was recognized during the year ended June 30, 2014 and included in research and development expense in connection with these activities.

Restricted Stock Units - The following table summarizes restricted stock award activity for the years ended June 30, 2014, 2013 and 2012:

	2014	2013	2012
Outstanding at beginning of year	757,500	250,000	500,000
Granted	603,400	757,500	-
Forfeited	(25,000)	-	-
Vested	(378,750)	(250,000)	(250,000)
Outstanding at end of year	957,150	757,500	250,000

For the years ended June 30, 2014, 2013 and 2012 the Company recorded stock-based compensation related to restricted stock units of \$300,485, \$219,767 and \$317,722, respectively.

In June 2014, the Company granted 325,000 restricted stock units to its executive officers, 143,400 restricted stock units to its employees and 135,000 restricted stock units to its non-employee directors under the Company's 2011 Stock Incentive Plan. The Company will amortize the fair value of these restricted stock units of \$331,500, \$146,268 and \$137,700, respectively, over the vesting period. Restricted stock units granted to the Company's executive officers, employees and non-employee directors in 2014 vest over 24 months, 48 months and 12 months, respectively.

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 is amortizing 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.

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 was amortized over the 24 month vesting period of the award.

In connection with the vesting of restricted share units during the years ended June 30, 2014 and 2013, the Company withheld 129,103 and 158,264 shares with aggregate values of \$120,007 and \$87,411, respectively, in satisfaction of minimum tax withholding obligations.

#### **Notes to Consolidated Financial Statements**

During the year ended June 30, 2014, the Company accelerated the vesting of certain restricted stock units that were granted to a terminated employee in recognition of prior services. An incremental \$12,000 of stock-based compensation expense was recognized during the year ended June 30, 2014 and included in research and development expense in connection with these activities.

#### (10) 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, 2014, the Company had federal and state net operating loss carryforwards of approximately \$235 million and \$93 million, respectively, which expire between 2014 and 2034 if not utilized. As of June 30, 2014, the Company had federal research and development credits of approximately \$6,871,000 that will begin to expire in 2014, if not utilized.

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:

	ne 30, 014		ne 30, 01 <b>3</b>	
Net operating loss carryforwards	\$ 87,801,000		\$ 83,470,000	
Research and development tax credits	6,871,000		6,605,000	
Accrued expenses, deferred revenue and				
other	1,003,000		1,698,000	
	95,675,000		91,773,000	
Valuation allowance	(95,675,000	)	(91,773,000	
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, 2014 and 2013.

During the years ended June 30, 2014, 2013 and 2012, the Company sold New Jersey state net operating loss carryforwards, which resulted in the recognition of \$1,846,646, \$1,753,208, and \$1,068,233, respectively, in tax benefits.

## **Notes to Consolidated Financial Statements**

# (11) CONSOLIDATED QUARTERLY FINANCIAL DATA – UNAUDITED

The following tables provide quarterly data for the years ended June 30, 2014 and 2013:

		Three Months Ended					
		June 30,	March 31,	Dece	ember 31,	Sep	tember 30,
		2014	2014		2013	2013	
		(am	ounts in thousand	s, except	per share da	ta)	
Revenues	\$	-	\$	Ψ	-	\$	
Operating expenses		4,321	3,364		3,610		4,492
Other income (expense), net		1	4		4		3
Loss before income taxes		(4,320)	(3,360		(3,606)		(4,489
Income tax benefit			1,847	<b>'</b>	-		
Net loss	\$	(4,320)	\$ (1,513	3) \$	(3,606)	\$	(4,489
Basic and diluted net loss per							
common share	\$	(0.04)	\$ (0.01	) \$	(0.03)	\$	(0.04
Weighted average number of		_					
common shares outstanding							
used in computing basic and							
diluted net loss per common							
share	10	06,735,765	106,709,340	106	6,668,186	10	6,609,720
		luno 20	Three Mo			Son	tombor 20
		June 30,	March 31,	Dece	ember 31,	Sep	tember 30,
		2013	2013		2012		2012
Revenues	\$	(am -	ounts in thousand \$		per share da	ta) \$	3
Operating expenses	Φ	4,720	4,024	•	3,447	φ	3,404
Other income (expense), net		4,720	4,024		11		(7,052
Loss before income taxes		(4,718)	(4,015		(3,429)		(10,453
Income tax benefit		(4,710)	(4,010	')	1,753		(10,430
Net loss	\$	(4,718)	\$ (4,015	5) \$	(1,676)	\$	(10,453
Basic and diluted net loss per	<u>Ψ</u>	(1,7.10)	<u> </u>	΄ Ψ	(1,070)	<u> </u>	(10,100
common share	\$	(0.04)	\$ (0.04	l) \$	(0.02)	\$	(0.15
	<u>*</u>		<del>*</del> (***	<u> </u>	( /	÷	
Weighted average number of							
Weighted average number of common shares outstanding							
common shares outstanding							
common shares outstanding used in computing basic and							
common shares outstanding	10	06,435,741	106,424,443	106	5,424,443	7	1,669,170

## (12) SUBSEQUENT EVENT

In August 2014, the Company entered into a license, co-development and commercialization agreement with Gedeon Richter on bremelanotide for FSD in Europe and selected countries. In August 2013, the Company received an initial payment of \$1.0 million from Gedeon Richter as a non-refundable option fee on the license, co-development and commercialization agreement, and in September 2014. the Company received \$8.8 million on execution of the definitive agreement. Under the agreement, Gedeon Richter will pay the Company a milestone payment of €2.5 million (\$3.3 million) upon the initiation of the Company's Phase 3 clinical trial program in the United States. The Company has the potential to receive up to €80 million (\$105.6 million) in regulatory and sales related milestones, and will receive low double-digit royalties on net sales in the licensed territory. Under the agreement the Company will contribute, with Gedeon Richter, to the costs of co-development activities for obtaining regulatory approval in Europe. Gedeon Richter will exclusively market bremelanotide for FSD in the licensed territory, and will be responsible for all sales, marketing and commercial activities, including associated costs, in the licensed territory. The agreement remains in effect as long as Gedeon Richter is selling bremelanotide on which a royalty is owed. The agreement may be terminated by either party upon notice in the event of a material breach or insolvency. In the event Gedeon Richter terminates the agreement because the Company breached the agreement or is insolvent, Gedeon Richter's license will becomes fully paid-up, royalty free, perpetual and irrevocable. If the Company fails to initiate its Phase 3 program by an agreed date, Gedeon Richter at its option may elect to terminate the license and receive a specified payment. In the event that the Company terminates the agreement because Gedeon Richter breached the agreement or is insolvent, upon timely request all regulatory approvals for bremelanotide in the licensed territory will be transferred to the Company or its designee.

#### **Notes to Consolidated Financial Statements**

#### 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, 2014, 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, 2014. 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, 2014, our internal control over financial reporting is effective based on those criteria.

### Item 9B. Other Information.

None.

#### 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 19, 2014.

Name	Age	Position with Palatin
Carl Spana, Ph.D.	52	Chief executive officer, president and a director
John K.A. Prendergast, Ph.D. (3)	60	Director, chairman of the board of directors
Perry B. Molinoff, M.D. (1) (3)	74	Director
Robert K. deVeer, Jr. (1) (2)	68	Director
Zola P. Horovitz, Ph.D. (2) (3)	79	Director
Robert I. Taber, Ph.D. (1) (2)	78	Director
J. Stanley Hull (2)	62	Director
Alan W. Dunton, M.D. (1) (2)	60	Director
Angela Rossetti (3)	61	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 seventeen 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.

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 of GenVec, Inc., a publicly-held life science company. Dr. Horovitz previously 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 Glaxo Smith Kline, 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 Glaxo Smith Kline 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.

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. He previously served on the board of directors of the publicly-traded companies EpiCept Corporation (as Non-Executive Chairman), Adams Respiratory Therapeutics, Inc. (acquired by Reckitt Benckiser Group plc), MediciNova, Inc. and Panacos Pharmaceuticals, Inc. Dr. Dunton has 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 a recent graduate of the Albert Einstein College of Medicine, with a Masters of Bioethics, and has an M.B.A. in Finance from Columbia University Graduate School of Business and a B.A. in Biology 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 2014, the board met five 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 or she served. The independent directors meet in executive sessions at least annually, following the annual board meeting. We do not have a policy requiring our directors to attend stockholder meetings. With the exception of Drs. Prendergast and Spana, the directors did not attend the annual meeting of stockholders held on June 19, 2014.

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. 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 and updated as of October 1, 2013, 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 Plan and the options still outstanding which were granted under previous stock option plans. The compensation committee is composed of Messrs. deVeer and Hull and Drs. Horovitz, Taber and Dunton (chair). The board has determined that the members of the compensation committee are independent, as defined in the listing standards of the NYSE MKT. Our chief executive officer aids the compensation committee by providing annual recommendations regarding the compensation of all executive officers, other than himself. 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.

The responsibilities of the compensation committee are set forth in a written charter adopted by the board effective October 1, 2013, a copy of which is available on our web site at www.palatin.com. The committee administers our 2011 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 Securities Exchange Act of 1934.

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 and updated as of October 1, 2013, a copy of which is available on our web site at www.palatin.com. The nominating and corporate governance committee is composed of Drs. Horovitz (chair), Prendergast 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.

#### **Communicating 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, updated as of October 1, 2013, 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.	52	Chief executive officer, president and director
		Chief financial officer, chief operating officer, executive vice president,
Stephen T. Wills, MST, CPA	57	secretary and treasurer

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 was previously 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 previously 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 2014.

#### Item 11. Executive Compensation.

## **Fiscal 2014 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, 2014 and 2013. We have no defined benefit or actuarial pension plan, and no deferred compensation plan.

	Fiscal	Salary	Stock	Option	Nonequity incentive plan compensation	All other compensation	Total
Name and Principal Position	Year	(\$)	awards (1) (\$)	awards (1) (\$)	(2)(\$)	(3)(\$)	(\$)
Carl Spana, Ph.D., chief executive officer and	2014	450,000	178,500	143,083	170,000	22,500	964,083
president							
	2013	436,771	217,400	245,971	250,000	12,938	1,163,080
Stephen T. Wills, MST,	2014	410,000	153,000	122,643	140,000	17,376	843,019
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

- (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 9 to the consolidated financial statements included in this Annual Report.
- (2) Bonus amounts.
- (3) Consists of matching contributions to 401(k) plan.

### **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 were approved by the compensation committee and the board and replace 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 performance 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 performance-based bonuses to our named executive officers for fiscal 2014 and 2013, based on results of operations, including clinical trial operations and our financial condition. Bonuses for fiscal year 2013 were higher than for fiscal year 2014 for reasons including successful completion of phase 2 trials of the company's lead product under development, bremelanotide for female sexual dysfunction, and completion of a private placement with gross proceeds of \$35,000,000.

#### 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 25, 2014, we granted 175,000 restricted stock units to Dr. Spana and 150,000 restricted stock units to Mr. Wills, which vest as to 50% on each anniversary of the grant date. We also granted 175,000 stock options to Dr. Spana and 150,000 stock options to Mr. Wills, which vest as to 25% on each anniversary of the grant date. These options have an exercise price of \$1.02, the fair market value on the date of grant, and they expire on June 25, 2024.

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.

## **Outstanding Equity Awards at 2014 Fiscal Year-End**

The following table summarizes all of the outstanding equity-based awards granted to our named executive officers as of June 30, 2014, the end of our fiscal year.

		Option awards (1)			Stock awards (2)			
Name	Option or stock award grant date	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 (#)	shai of h	ket value of res or units stock that nave not vested (\$) (3)
Carl Spana	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	25,000	-	2.80	07/01/19			
	06/22/11	225,000	75,000	1.00	06/22/21			
	07/17/12	37,500	112,500	0.72	07/17/22			
	07/17/12					56,250		55,688
	06/27/13	68,750	206,250	0.62	06/27/23			
	06/27/13					110,000		108,900
	06/25/14	-	175,000	1.02	06/25/24			
	06/25/14					175,000		173,250
		Tota	ll Stock Awards			341,250	\$	337,838
Stephen T. Wills	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	20,000	-	2.80	07/01/19			
	06/22/11	187,500	62,500	1.00	06/22/21			
	07/17/12	33,750	101,250	0.72	07/17/22			
	07/17/12		107 50		00/07/05	55,000		54,450
	06/27/13	62,500	187,500	0.62	06/27/23			
	06/27/13		,		00/07:5	100,000		99,000
	06/25/14	-	150,000	1.02	06/25/24			
	06/25/14					150,000		148,500
		Tota	I Stock Awards			305,000	\$	301,950

- (1) Stock option vesting schedules: all options granted on or before July 1, 2009 have fully vested. Options granted after July 1, 2009 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 had not vested as of June 30, 2014, but which vested on July 17, 2014; restricted stock units granted on June 27, 2013, which vested as to 50% on June 27, 2014 and will vest as to the remaining 50% on June 27, 2015; and restricted stock units granted on June 25, 2014, which will vest as to 50% on June 25, 2015 and 2016, 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 \$0.99, the closing market price of our common stock on June 30, 2014, the last trading day of our most recently completed fiscal year.

### **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 will receive 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.

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.

#### **Director Compensation**

The following table sets forth the compensation we paid to all directors during fiscal 2014, 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.

_	Fees earned or	Stock awards	Option awards	
Name	paid in cash (\$)	(\$) (2)	(\$) (1) (2)	Total (\$)
John K.A. Prendergast, Ph.D.	87,500	30,600	21,673	139,773
Perry B. Molinoff, M.D.	47,000	15,300	10,837	73,137
Robert K. deVeer, Jr.	55,000	15,300	10,837	81,137
Zola P. Horovitz, Ph.D.	49,000	15,300	10,837	75,137
Robert I. Taber, Ph.D.	55,000	15,300	10,837	81,137
J. Stanley Hull	42,000	15,300	10,837	68,137
Alan W. Dunton, M.D.	50,000	15,300	10,837	76,137
Angela Rossetti	42,000	15,300	10,837	68,137

(1) The aggregate number of shares underlying option awards and stock awards outstanding at June 30, 2014 for each director was:

	Option awards	Stock awards
Dr. Prendergast	278,350	30,000
Dr. Molinoff	166,833	15,000
Mr. deVeer	171,000	15,000
Dr. Horovitz	167,500	15,000
Dr. Taber	167,500	15,000
Mr. Hull	167,166	15,000
Dr. Dunton	92,500	15,000
Ms. Rossetti	45,000	15,000

(2) 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 9 to the consolidated financial statements included in this Annual Report. Amounts in this column include options granted on June 25, 2014 for our current (2015) 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 25, 2014, as the annual option grant for our current (2015) fiscal year, the chairman of the board received 30,000 restricted stock units which vest on June 25, 2015, and an option to purchase 30,000 shares of common stock, and each other serving non-employee director received 15,000 restricted stock units which vest on June 25, 2015, and an option to purchase 15,000 shares of common stock. All of the options have an exercise price of \$1.02 per share, the closing price of our common stock on the date of grant, vest in twelve monthly installments beginning on July 31, 2014, 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 June 27, 2013, as the annual option grant for our 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.

Non-Employee Directors' Cash Compensation. Dr. Prendergast serves as chairman of the board and for our 2014 fiscal year received an annual retainer of \$87,500, payable quarterly. Other non-employee directors received an annual base retainer of \$40,000, 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, will receive an additional retainer of one-half the retainer payable to the committee chairperson. For the 2015 fiscal year, the chairperson of the audit committee will receive an additional annual retainer of \$12,500, and other members of the audit committee will receive an additional annual retainer of \$6,000; the chairperson of the compensation committee received an additional annual retainer of \$10,000 and the chairperson of the corporate governance committee will receive an additional annual retainer of \$6,000. Members of the compensation and corporate governance committees, other than the non-employee chairman, will receive 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, 2014:

# Equity Compensation Plan Information as of June 30, 2014

			Number of
			securities
			remaining
			available for
	Number of		future issuance
	securities to be	Weighted-	under equity
	issued upon	average	compensation
	exercise of	exercise price of	plans
	outstanding	outstanding	(excluding
	options,	options,	securities
	warrants and	warrants and	reflected in
Plan category	rights	rights	column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	5,199,123(1)	\$ 1.63(2)	1,929,056
Equity compensation plans not approved by security holders		-	
Total	5,199,123		1,929,056

- (1) Consists of 3,733,650 options and 957,150 restricted stock units granted under our 2011 Stock Incentive Plan, 490,090 options granted under our 2005 Stock Plan and 18,233 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 957,150 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 25, 2018, 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.

Beneficial Ownership Tables. The tables below show the beneficial stock ownership and voting power, as of September 11, 2014, 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 xx, 2014. 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 11, 2014, on which date 39,490,161 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.	964,713(1)	2.4%	1.1%
Common		Stephen T. Wills	878,137 <sup>(2)</sup>	2.2%	1.1%
Common		John K.A. Prendergast, Ph.D.	252,617 <sup>(3)</sup>	*	*
Common		Perry B. Molinoff, M.D.	162,833 <sup>(4)</sup>	*	*
Common		Robert K. deVeer, Jr.	176,060 <sup>(5)</sup>	*	*
Common		Zola P. Horovitz, Ph.D.	161,000 <sup>(6)</sup>	*	*
Common		Robert I. Taber, Ph.D.	156,000 <sup>(7)</sup>	*	*
Common		J. Stanley Hull	154,166 <sup>(8)</sup>	*	*
Common		Alan W. Dunton, M.D.	85,020 <sup>(9)</sup>	*	*
Common		Angela Rossetti	35,000(10)	*	*
		All current directors and executive officers as a group (ten persons)	3,025,546 <sup>(11)</sup>	7.3%	2.3%

<sup>\*</sup>Less than one percent.

- (1) Includes 484,550 shares which Dr. Spana has the right to acquire under options, and 50,000 shares which he has the right to acquire under warrants.
- (2) Includes 409,800 shares which Mr. Wills has the right to acquire under options, and 50,000 shares which he has the right to acquire under warrants.
- (3) Includes 250,850 shares which Dr. Prendergast has the right to acquire under options.
- (4) Includes 151,833 shares which Dr. Molinoff has the right to acquire under options.
- (5) Includes 154,000 shares which Mr. deVeer has the right to acquire under options.
- (6) Includes 150,500 shares which Dr. Horovitz has the right to acquire under options.
- (7) Includes 150,500 shares which Dr. Taber has the right to acquire under options.
- (8) Includes 152,166 shares which Mr. Hull has the right to acquire under options.
- (9) Includes 77,500 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 2,116,699 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	4,060,028(2)	10.3%	10.3%
Common		QVT Financial LP 1177 Avenue of the Americas, 9th Floor New York, New York 10036	3,953,065(3)	9.9%	9.8%
Common		James E. Flynn 780 Third Avenue, 37th Floor New York, NY 10017	4,160,945(4)	9.9%	5.1%
Common		Great Point Partners LLC Jeffrey R. Jay, M.D. David Kroin 165 Mason Street, 3rd Floor Greenwich, CT 06830	2,337,000(5)	5.6%	*
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 New Canaan, CT 06840	500	10.6%	*
Series A Preferred		Jonathan E. Rothschild 300 Mercer St., #28F New York, NY 10003	500	10.6%	*
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. disclaimed beneficial ownership. The Schedule 13G/A reported that Investment 10, L.L.C. owned 354,900 shares. The shares owned directly by the other filers, as updated on a joint Form 4 filed on March 3, 2014, are:
  - (i) BVF Investments, L.L.C.: 2,494,521 shares;
  - (ii) Biotechnology Value Fund, L.P.: 772,480 shares; and
  - (iii) Biotechnology Value Fund II, L.P.: 438,127 shares.
- (3) Includes 80,065 shares issuable on exercise of 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.

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 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. Beneficial ownership as listed in the table above excludes warrants which are not exercisable because of that restriction.

- (4) Includes 2,160,945 shares issuable on exercise of warrants. According to a joint Schedule 13G/A filed on February 14, 2014, Mr. Flynn and the other filers had beneficial ownership and shared voting and dispositive power as follows:
  - (i) James E. Flynn: 2,000,000 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.: 2,000,000 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.: 2,000,000 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.
  - (iv) Deerfield Special Situations Fund L.P.: 1,098,000 shares outstanding and 1,287,000 shares issuable on exercise of warrants.
  - (v) Deerfield Special Situations International Master Fund, L.P.: 902,000 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.

- (5) 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, 2014, 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: 762,692 shares issuable on exercise of warrants;
  - (ii) Biomedical Offshore Value Fund, Ltd.: 439,819 shares issuable on exercise of warrants;
  - (iii) Biomedical Institutional Value Fund, LP: 282,815 shares issuable on exercise of warrants;
  - (iv) Lyrical Multi-Manager Fund, LP: 265,834 shares issuable on exercise of warrants;
  - (v) Lyrical Multi-Manager Fund Offshore Fund, Ltd.: 115,513 shares issuable on exercise of warrants;
  - (vi) Class D Series of GEF-PS, LP: 381,347 shares issuable on exercise of warrants;
  - (vii) David J. Morrison: 12,712 shares issuable on exercise of warrants; and
- (viii) WS Investments III, LLC: 76,269 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) 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, 2012, 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 2014 and fiscal 2013.

*Audit Fees.* For fiscal 2014, KPMG billed us a total of \$215,000 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 2013, the total billed for the same services was \$220,000.

Audit-Related Fees. For fiscal 2014 and 2013, KPMG did not perform or bill us for any audit-related services.

*Tax Fees.* For fiscal 2014, KPMG billed us a total of \$18,950 for professional services rendered for tax compliance. For fiscal 2013, 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 2014 and 2013.

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 preapprove 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.

## **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: The exhibits, listed on the accompanying exhibit index that is set forth after the signature page, are filed or incorporated by reference (as stated thereon) as part of this Annual Report on Form 10-K.

## **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.

By: /s/Carl Spana

Carl Spana, Ph.D.

President and Chief Executive

Officer

(principal executive officer)

Date: September 12, 2014

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	President, Chief Executive Officer and Director	September 12, 2014
Carl Spana	(principal executive officer)	
/s/ Stephen T. Wills	Executive Vice President, Chief Financial Officer and	September 12, 2014
Stephen T. Wills	Chief Operating Officer (principal financial and accounting officer)	
/s/ John K.A. Prendergast	Chairman and Director	September 12, 2014
John K.A. Prendergast	Grainfian and Director	Geptember 12, 2014
/s/ Perry B. Molinoff	Director	September 12, 2014
Perry B. Molinoff		•
/s/ Robert K. deVeer, Jr.	Director	September 12, 2014
Robert K. deVeer, Jr.		
/s/ Zola P. Horovitz	Director	September 12, 2014
Zola P. Horovitz		
/s/ Robert I. Taber Robert I. Taber	Director	September 12, 2014
Robert I. Taber		
/s/ J. Stanley Hull  J. Stanley Hull	Director	September 12, 2014
,		
/s/ Alan W. Dunton Alan W. Dunton	Director	September 12, 2014
/c/ Angola Possotti	Director	Sontombor 12, 2014
/s/ Angela Rossetti Angela Rossetti	Director	September 12, 2014

# **EXHIBIT INDEX**

No.	Description of Exhibit
3.01	Restated certificate of incorporation, as amended. Incorporated by reference to Exhibit 3.01 of our Annual Report on Form 10-K for the year ended June 30, 2013, filed with the SEC on September 27, 2013.
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	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.
4.02	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.
4.03	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.
4.04	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.
4.05	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.
4.06	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.
4.07	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.
4.08	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. †

- 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.
- 10.16 Employment Agreement, effective as of July 1, 2013, between Palatin and Carl Spana. Incorporated by reference to Exhibit 10.16 of our Annual Report on Form 10-K for the year ended June 30, 2013, filed with the SEC on September 27, 2013. †
- 10.17 Employment Agreement, effective as of July 1, 2013, between Palatin and Stephen T. Wills. Incorporated by reference to Exhibit 10.17 of our Annual Report on Form 10-K for the year ended June 30, 2013, filed with the SEC on September 27, 2013. †
- 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. Incorporated by reference to Exhibit 10.20 of our Annual Report on Form 10-K for the year ended June 30, 2013, filed with the SEC on September 27, 2013. †
- 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.
- 10.27 License, Co-Development and Commercialization Agreement, dated August 29, 2014, by and between Palatin Technologies, Inc. and Chemical Works of Gedeon Richter Plc. We have requested confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request. \*
  - 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.

<sup>†</sup> Management contract or compensatory plan or arrangement.

# \*\*\* OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION CONFIDENTIAL TREATMENT REQUESTED UNDER 17 C.F.R. SECTION 240.24b-2

LICENSE, CO-DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

between

Palatin Technologies, Inc.

and

Chemical Works of Gedeon Richter Plc.

This binding agreement was executed on August 29h, 2014

## LICENSE, CO-DEVELOPMENT AND COMMERCIALIZATION AGREEMENT

THIS LICENSE, CO-DEVELOPMENT AND COMMERCIALIZATION AGREEMENT (the "Agreement"), effective as of August 29<sup>h</sup>, 2014 (the "Effective Date"), is entered between:

**Palatin Technologies, Inc.**, a United States company operating under the laws of the United States of America and under the laws of the State of Delaware, with a principal place of business at 4-B Cedar Brook Drive, Cranbury, New Jersey 08512, USA ("Palatin"),

and:

Chemical Works of Gedeon Richter Plc, a Hungarian company operating under the laws of Hungary with a principal place of business at Gyömrői út 19-21, Budapest 1103, Hungary ("Gedeon Richter").

Palatin and Gedeon Richter are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

#### Recitals

## WHEREAS:

- A. Palatin, a United States company operating under the laws of the State of Delaware, is developing the Product (as hereinafter defined);
- B. Gedeon Richter, a Hungarian company operating under the laws of Hungary, is engaged in the development, manufacture and commercialization of pharmaceutical products;
- C. The Parties entered into a Confidential Disclosure Agreement as of \*\*\* for the purpose of evaluating the in-licensing of the Product for the treatment of female sexual dysfunction and exchanging confidential information between each other;
- D. Gedeon Richter offered Palatin a Non-Binding Proposal of Terms for Collaboration (dated as of \*\*\*), in the framework of which Gedeon Richter outlined a business collaboration for the Product;
- E. The Parties concluded an agreement dated as of \*\*\* and its first amendment dated as of \*\*\* relating to an option to negotiate an exclusive license for the purpose of granting to Gedeon Richter an exclusive right to negotiate the terms of a license agreement for the Product;
- F. Gedeon Richter desires to obtain from Palatin certain exclusive rights and licenses to manufacture, develop, have developed, register, commercialize, use, sell, offer for sale and import the Product in the Field (as hereinafter defined) in the Territory (as hereinafter defined), and Palatin is willing to grant to Gedeon Richter such rights and licenses and to exclusively supply Gedeon Richter with the Product for the Territory, all on the terms and conditions set forth in this Agreement and the Supply Agreement for Development (as hereinafter defined) and the Commercial Supply Agreement (as hereinafter defined); and
- G. Palatin desires to use the results of clinical trials and Major regulatory submissions within the Territory (as hereinafter defined) for its use outside the Territory and Gedeon Richter desires to use the results of clinical trials and regulatory submissions outside the Territory for its use inside the Territory.

NOW, THEREFORE, Palatin and Gedeon Richter agree as follows:

#### 1. DEFINITIONS

For the purposes of this Agreement, the following terms shall have the respective meanings set forth below:

- 1.1 "Affiliate" means, with respect to a Party, any person, corporation, firm, joint venture or other entity which, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. As used in this definition, "control" means possession of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of fifty percent (50%) or more of the outstanding voting securities or by contract or otherwise.
  - 1.2 "Audit Disagreement" shall have the meaning set forth in Section 9.7(b).

- 1.3 "Business Day" means any day that is not a Saturday, a Sunday or other day on which banks are required or authorized by law to be closed in either Hungary or New Jersey.
- 1.4 "Change of Control" any person, corporation or other entity other than a Party becomes the beneficial owner(s) directly or indirectly, of more than fifty percent (50%) of the outstanding equity securities of the Party, or otherwise becomes entitled, directly or indirectly, to vote more than fifty percent (50%) of the voting power entitled to be cast at elections for directors ("Voting Power") of the Party, other than as a result of the issuance of equity securities in connection with any financing transaction; (ii) a consolidation or merger (in one transaction or a series of related transactions) of a Party pursuant to which the holders of a Party's equity securities immediately prior to such transaction or series of related transactions would not be the holders, directly or indirectly, immediately after such transaction or series of related transactions of more than fifty percent (50%) of the Voting Power of the entity surviving such transaction or series of related transactions; and (iii) the sale, lease, exchange or other transfer (in one transaction or a series of related transactions) of all or substantially all of the assets of a Party.
- 1.5 "Clinical Study" means any investigation involving human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy.
- 1.6 "CMC" means chemistry, manufacturing and controls, including design, development and technical file of the relevant device necessary for administration of the Product.
- 1.7 <u>Commercialization</u>" and "<u>Commercialize</u>" shall refer to all activities undertaken relating to the pre-marketing, marketing, distribution and sale of a Product, and the process of Commercialization, respectively.
- 1.8 "Commercially Reasonable Efforts" means the carrying out of such obligations with a level of efforts and resources consistent with the commercially reasonable practices it employs for its own products (in any case, such level shall not be below the standard level in the pharmaceutical industry) in the exercise of prudent scientific and business judgment that would be applied to the research, development, manufacture or commercialization of a pharmaceutical product. Commercially Reasonable Efforts require that the Party: (a) in a timely manner assign responsibility for such obligations or tasks to specific employee(s) with sufficient skills and experience as are required to accomplish such obligations or tasks, and hold such employee(s) accountable for progress and monitor such progress on an on-going basis; (b) set and timely seek to achieve specific and meaningful objectives for carrying out such obligations; and (c) timely make and implement decisions and allocate resources designed to advance progress with respect to such objectives.
- 1.9 "Competent Authority" shall mean any applicable regulatory authority, including but not limited to EMA or any other certification or Notified Bodies in the Territory responsible for the grant of the Regulatory Approval.
- 1.10 "Control" or "Controlled" shall mean possession of the ability to grant the licenses or sublicenses as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.
  - 1.11 "CTA" means a Clinical Trial Application filed with the Competent Authority.
- 1.12 "<u>Development</u>" means all activities relating to preclinical development, clinical development and CMC/process development, as are customary in the pharmaceutical and medical device industry and necessary for obtaining Regulatory Approval.
- 1.13 "<u>Dossier</u>" means documentation in the English language compiled according to the European Union requirements in Common Technical Documentation (hereinafter referred to as "CTD") format.
  - 1.14 "EMA" means European Medicines Agency or any successor entity.
  - 1.15 "EU" means the countries of the European Union, as constituted from time to time.
  - 1.16 "FDA" means the U.S. Food and Drug Administration or any successor entity.
  - 1.17 "Field" means human use in treatment of female sexual dysfunction
- 1.18 "First Commercial Sale" means, on a country-by-country basis, the date of the first sale or other commercial disposal of the Product by Gedeon Richter or an Affiliate or Sublicensee of Gedeon Richter pursuant to a Regulatory Approval.
- 1.19 "GCP" means the Good Clinical Practices guidelines defined by 28/2005/EC directive and appropriate ICH guide and required by the European Commission, and other standards of the European Commission that are generally recognized within the European pharmaceutical industry, including the ICH Harmonized Tripartite Guideline for Good Clinical Practice, as amended from time to time.
- 1.20 "<u>Gedeon Richter Development Plan</u>" means the Development activities to be performed by Gedeon Richter \*\*\* and listed in Exhibit VI, as the same may be amended in accordance with the provisions of this Agreement.

- 1.21 "<u>Gedeon Richter Know-How</u>" means any Information within the control of Gedeon Richter obtained or gained during the performance of the Gedeon Richter Development Plan, the Commercialization Plan or Gedeon Richter's obligations under this Agreement.
- 1.22 "GLP" means the Good Laboratory Practices regulations defined by 9/2204/EC and 10/2004/EC as well as appropriate OECD guide and according to standards, guidelines and regulations promulgated or otherwise required by the European Commission, and published standards of the European Commission, and other standards of the European Commission that are generally recognized within the European pharmaceutical industry, including Council Directive 2001/83/EC, as amended from time to time.
- 1.23 "GMP" means the Good Manufacturing Practices regulations and General Biologics Products Standards defined by European Directive 94/2003/EC, 9/2204/EC and 10/2004/EC as well as appropriate OECD guide GMP also includes similar standards, guidelines and regulations promulgated and required by the European Commission, and published standards of the European Commission and other standards of the European Commission that are generally recognized within the European pharmaceutical industry, including the Guide to Good Manufacturing Practices for Medicinal Products and Council Directive 2001/83/EC, as amended from time to time.
- 1.24 "GVP" means Good Pharmacovigilance Practices for the European Union, a set of guidelines for the conduct of pharmacovigilance in the EU, drawn up based on Article 108a of Directive 2001/83/EC, by the European Medicines Agency in cooperation with competent authorities in Member States and interested parties, and applying to marketing authorization holders in the EU, the Agency and competent authorities in Member States.
  - 1.25 "Indemnitee" means a Gedeon Richter Indemnitee or a Palatin Indemnitee.
- 1.26 "Information" means techniques, data and information relating to the Product, including, but not limited to, inventions, practices, methods, knowledge, know-how, skill, trade secrets, experience and test data (including but not limited to pharmacological, toxicological, preclinical and clinical test data); data, records and information derived from research, preclinical development and clinical development including but not limited to full clinical study reports, full clinical study datasets in SDTM format, statistical evaluation program codes, regulatory submissions, adverse reactions, CMC/process development, analytical and quality control data, and Commercialization, marketing, pricing, distribution, cost, sales and manufacturing data or descriptions.
  - 1.27 "Initiation" means \*\*\*.
- 1.28 "Investigational Product" means a pharmaceutical form of an active ingredient and/or the relevant placebo being tested or used as a reference in a Clinical Study, including but not limited to the finished product form equipped with the relevant device necessary for administration or a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.
  - 1.29 "Joint Steering Committee" shall have the meaning contained in Section 4.1.
- 1.30 "Major regulatory submission" means any documents or data submitted to or communications to be carried out with EMA, Competent Authorities that contain substantial or important new information related to the Product or the Development of the Product in the Field, e.g. Marketing Authorization Application, Investigators' Brochure, clinical trial reports or report summaries, other study reports, IMPD, CMC documentation, Development Safety Update Reports or their amendments, substantial amendments of clinical trial protocols that are not of a merely administrative nature.
- 1.31 "Marketing Authorization Application" means an application for Regulatory Approval required to be approved by the Competent Authorities and necessary for the commercial manufacture, use, storage, import, export, transport, commercialization or sale of a Product in any country of the Territory.
  - 1.32 "Milestones Payments" mean the payments to be made by Gedeon Richter to Palatin in accordance with Section 7.2.
- 1.33 "Net Sales" means the gross amounts invoiced or otherwise billed by Gedeon Richter and its Affiliates and Sublicensees in connection with sales of the Product in the Territory, calculated in accordance with accounting standards of Gedeon Richter and its Affiliates or Sublicensees (IFRS, since Gedeon Richter is obliged to report its consolidated performance to the stock exchange according to IFRS) as applicable, consistently applied, less the following amounts specifically identified as related to, and specifically allocated to, the Products (without duplication of any amounts deducted in accordance with IFRS): \*\*\*. Upon the sale or other disposal of the Product other than in a bona fide arm's length transaction exclusively for money or upon any use of the Product for purposes which do not result in a disposal of that Product in consideration of sales revenue customary in the country of use, such sale, other disposal or use shall be deemed to constitute a sale at the relevant open market price in the country in which the sale, other disposal or use occurs, or, if that price is not ascertainable, at the price the goods or services provided in exchange for the Products would obtain in an arm's length transaction.

- 1.34 "Notified Bodies" means an accredited body and Commission announced organization with identification number issued by the Commission. Its designated tasks are the evaluation and certification of the conformity of devices in the European Commission, and management of other conformity assessment tasks.
- 1.35 "Palatin Development Plan" means the Development activities, including \*\*\*, to be performed by Palatin \*\*\* and listed in Exhibit V, as the same may be amended in accordance with the provisions of this Agreement. For the avoidance of doubt, \*\*\*.
- 1.36 "Palatin Know-How" means (a) any Information within the Control of Palatin as of the Effective Date relating to the Development of the Product in the Field, including but not limited to the information contained in the documentation listed in Exhibit II, (b) all Information generated or obtained by Palatin after the Effective Date during the performance of Palatin's obligations under this Agreement, and (c) all other Information generated or obtained by Palatin after the Effective Date relating to the Development of the Product in the Field and Commercialization activities undertaken by or on behalf of Palatin. Notwithstanding anything herein to the contrary, Palatin Know-How shall exclude the Palatin Patents.
- 1.37 "Palatin Patent" means (i) each patent application and patent listed in Exhibit III, including (a) all reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; and (b) all extensions, renewals or restorations of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof and (ii) any patent application filed or to be filed, and any patent obtained or to be obtained, by Palatin in the Territory during the term of this Agreement relating to the Product in the Field.
- 1.38 "Phase III Study" means a Clinical Study designed to confirm the preliminary evidence that an investigational product is safe and effective for use in the intended indication and recipient population.
  - 1.39 "Pivotal Study" means a Phase III Study intended to support Regulatory Approval by the Competent Authorities.
- 1.40 "Product" means any pharmaceutical product for humans formulated in any finished product form that contains bremelanotide (PT-141) as active pharmaceutical ingredient, including but not limited to any relevant device necessary for administration.
- 1.41 "Regulatory Approval" means any approvals, product and/or establishment licenses, registrations or authorizations of any Competent Authority or other governmental entity, necessary for the commercial manufacture, use, storage, import, export, transport, commercialization or sale of the Product in a regulatory jurisdiction in the Territory.
- 1.42 "<u>Sublicensee</u>" shall mean a Third Party (except an Affiliate) to whom Gedeon Richter has granted a license or sublicense to Commercialize the Product in the Territory in accordance with the terms and conditions of this Agreement.
  - 1.43 "Territory" shall mean all countries that are listed in Exhibit I.
  - 1.44 "Third Party" means any entity other than Palatin or Gedeon Richter and its respective Affiliates and Sublicensees.
  - 1.45 "Top-5 Countries" shall mean \*\*\*.
  - 1.46 "Top 3 Countries" shall mean \*\*\*.
  - 1.47 "Trademark" means registered trademark owned by Gedeon Richter pertaining to the Product in the Territory.
- 1.48 "Valid Claim" means a claim of any unexpired Palatin Patent (as may be extended through supplementary protection certificate or patent term extension or the like), that has not been withdrawn, canceled or disclaimed nor held to be invalid or unenforceable by a court or tribunal of competent jurisdiction in a decision that is unappealable or unappealed within the time allowable for appeal, or, in the case of any patent application, that has not been finally rejected in a decision by the relevant patent office that is unappealable or unappealed within the time allowable for appeal.

#### 2. LICENSE

2.1 <u>License to Gedeon Richter</u>. Subject to the terms and conditions of this Agreement, Palatin hereby grants to Gedeon Richter (a) an exclusive (even as to Palatin and its Affiliates), royalty-bearing license, including the right to grant sublicenses in accordance with Section 2.2, under the Palatin Patents and Palatin Know-How to develop, have developed, register, commercialize, import, market, store, sell, and offer to sell the Product in the Field in the Territory, and (b) a co-exclusive (with Palatin and its Affiliates only) license, including the right to grant sublicenses in accordance with Section 2.2, under the Palatin Patents and Palatin Know-How to research, develop, have developed, manufacture and have manufactured the Product solely for use, commercialization, importation, sale or offer for sale in the Field in the Territory (the rights granted under the foregoing clauses (a) and (b), collectively, the "License"). Notwithstanding the foregoing, Gedeon Richter shall not exercise its rights to manufacture the Product or have the Product manufactured unless Palatin fails to supply the goods in accordance with the Commercial Supply Agreement or the Parties otherwise agree.

- 2.2.1 Subject to the terms and conditions of this Agreement, Gedeon Richter shall have the right to sublicense the rights granted in Section 2.1 above.
- 2.2.2 Except in the case of a sublicense to an Affiliate of Gedeon Richter, each sublicense granted pursuant to this Section 2.2 shall require the prior written consent of Palatin, which consent shall not be unreasonably withheld. Gedeon Richter shall provide to Palatin written notice of each proposed sublicense, which written notice shall include a reasonable level of detail regarding the terms of the proposed sublicense and the proposed Sublicensee's ability to perform its obligations hereunder. Unless Palatin provides to Gedeon Richter written notice that Palatin is withholding its consent to the proposed sublicense within \*\*\* after its receipt of the applicable notice from Gedeon Richter, Palatin shall be deemed to have consented to the proposed sublicense.
- 2.2.3 Each sublicense agreement shall be in writing and consistent with all the terms and conditions of this Agreement and shall provide that the Sublicensee shall be bound by and subject to all applicable terms and conditions of this Agreement in the same manner and to the same extent as Gedeon Richter is bound thereby. Each sublicense agreement shall provide that Gedeon Richter and Palatin shall have the same rights, ownership and/or licenses to all inventions and Information generated by such Sublicensee to the same extent as if such invention or Information was generated or obtained by Gedeon Richter, which rights, ownership and/or licenses shall survive the termination of the applicable sublicense agreement. Each sublicense agreement shall provide that further sublicensing by the Sublicensee is prohibited. Gedeon Richter shall provide a complete copy of each sublicense agreement to Palatin within \*\*\* after its execution. If any sublicense agreement provides for the payment of non-royalty consideration to Gedeon Richter (including, without limitation, upfront fees and milestone fees), Gedeon Richter shall pay to Palatin \*\*\* percent (\*\*\*%) of such non-royalty consideration.
- 2.2.4 Notwithstanding anything herein to the contrary, Gedeon Richter shall be responsible for the performance of each of its Sublicensee's and Affiliate's financial and other obligations hereunder, including, without limitation, the payment of all royalties due under Article 7 whether or not paid to Gedeon Richter by a Sublicensee or Affiliate.
- 2.3 <u>Palatin Retained Rights</u>. Subject to Section 2.5, and notwithstanding the rights granted to Gedeon Richter in Section 2.1 and without limiting the generality of Section 2.4, the Parties acknowledge that Palatin retains the following: (a) the right to practice the Palatin Patents and Palatin Know-How in the Territory to exercise its rights or to fulfill its obligations under this Agreement, the Supply Agreement for Development and the Commercial Supply Agreement, including the manufacturing and development of Products; and (b) the right to practice and license the Palatin Patents and Palatin Know-How outside the scope of the License. For clarity, and notwithstanding anything herein to the contrary, Palatin may (i) develop, have developed, manufacture, have manufactured, use and provide to Third Parties Products for purposes of Commercializing the Product outside the Field in the Territory and (ii) develop, have developed, manufacture, have manufactured and distribute Products in the Territory for purposes of Commercializing the Products outside the Territory and outside the Field in the Territory.
- 2.4 No Further Rights. Only the License granted pursuant to the express terms of this Agreement shall be of any legal force or effect. No other license rights shall be granted or created by implication, estoppels or otherwise.

## 2.5 Right of First Offer and Negotiation.

- 2.5.1 If Palatin determines to license rights to the Product to a Third Party for purposes of Commercializing the Product outside the Field in the Territory, then Palatin shall provide written notice of the same to Gedeon Richter (the "Field Offer Notice"). If, within \*\*\* after its receipt of the Field Offer Notice, Gedeon Richter indicates by written notice an interest in licensing such rights, Palatin will negotiate with Gedeon Richter, for a period of up to \*\*\*, a mutually acceptable term sheet for such license. If the parties are not able to reach agreement on and do not execute a term sheet with respect to the foregoing rights within such \*\*\* period, Palatin shall be free to continue with the Commercialization of the Product in the field of use in the territory described in the Field Offer Notice without further obligation to Gedeon Richter.
- 2.5.2 If Palatin determines to license rights to the Product to a Third Party for purposes of Commercializing the Product in the Field in any country identified on Exhibit IV, then Palatin shall provide written notice of the same to Gedeon Richter (the "Territory Offer Notice"). If, within \*\*\* after its receipt of the Territory Offer Notice, Gedeon Richter indicates by written notice an interest in licensing such rights, Palatin will negotiate with Gedeon Richter, for a period of up to \*\*\*, a mutually acceptable term sheet for such license. If the parties are not able to reach agreement on and do not execute a term sheet with respect to the foregoing rights within such \*\*\* period, Palatin shall be free to continue with the Commercialization of the Product in the Field in the territory described in the Territory Offer Notice without further obligation to Gedeon Richter.

#### 3. JOINT STEERING COMMITTEE

3.1 Formation of the Joint Steering Committee. As soon as reasonably practicable after the Effective Date, but not later than \*\*\*, the Parties shall establish a joint steering committee (the "Joint Steering Committee"). Each Party shall appoint two (or more if the Parties so agree) appropriately qualified employees of appropriate seniority to serve as its representatives on the Joint Steering Committee. Each Party may replace its Joint Steering Committee representatives with appropriately qualified employees of appropriate seniority at any time and from time to time upon written notice to the other Party. The initial chairperson of the Joint Steering Committee shall be appointed by Palatin, and thereafter the right to appoint the chairperson shall alternate on a meeting by meeting basis between Palatin and Gedeon Richter.

- 3.2 Meetings of the Joint Steering Committee. Meetings of the Joint Steering Committee shall be held \*\*\* or more frequently as requested by either Party to maintain the progress of the Development and the registration procedure. After the completion of the Development and registration procedure in the Territory, meetings shall be held \*\*\* but may be called by either Party with not less than ten (10) Business Days' notice to the other, unless such notice is waived. The Joint Steering Committee may hold meetings in person or by teleconference or videoconference. The chairperson shall be responsible for calling meetings of the Joint Steering Committee and, after seeking input from the other members of the Joint Steering Committee, setting the agenda for meetings and circulating the agenda to other members of the Joint Steering Committee, setting the applicable meeting. The agenda for meetings will include all items requested by members of the Joint Steering Committee. The chairperson shall insure the orderly conduct of meetings and distribute written minutes of the meetings within five (5) Business Days following each meeting. The chairperson shall provide all Joint Steering Committee members an opportunity to review and comment on the minutes before such minutes are filed as final records of the Joint Steering Committee. Each Party shall use reasonable efforts to cause its representatives to attend the meetings of the Joint Steering Committee. Each Party shall bear all the expenses of its representatives on the Joint Steering Committee. Except as set forth in this Section 3.2, the chairperson of the Joint Steering Committee will not have any greater power or authority than any other member of the Joint Steering Committee.
- 3.3 <u>Functions of the Joint Steering Committee</u>. The Joint Steering Committee shall oversee and direct the development, regulatory and commercialization strategy in the Territory with respect to the Development, obtaining Regulatory Approval and Commercialization of the Product in the Field, and shall coordinate communications among the Parties and the exchange of information concerning the progress of the Development of the Product and the Parties involvement in post-Development activities. The Joint Steering Committee's responsibilities shall include:
  - (a) receiving and reviewing reports and other information from the Parties with regard to Development and Commercialization activities and coordinating the exchange of CMC, clinical and nonclinical data, including, where appropriate, raw data from studies carried out by or on behalf of the Parties;
  - (b) reviewing and evaluating progress under the Gedeon Richter Development Plan and the Palatin Development Plan;
  - (c) deciding on the performance of an additional Pivotal Study to be performed in accordance with the provisions of Section 4.1.2(b);
  - (d) reviewing and approving amendments to the Gedeon Richter Development Plan and the Palatin Development Plan;
  - (e) monitoring the progress of studies and approving additional studies, including drug-drug interaction studies and other ancillary studies;
  - (f) reviewing and approving Marketing Authorization Application(s) and Major regulatory submissions in the Territory relating to the Product and as otherwise provided in this Agreement with respect to regulatory submissions to the FDA;
  - (g) establishing procedures regarding the collection, sharing and reporting of adverse event information relating to the Product; and
  - (h) reviewing and approving the Commercialization Plan and all amendments thereto
- 3.4 Reporting to the Joint Steering Committee. Each Party shall regularly inform the other Party about the actual status of its development activities with respect to the Product in the Field during the Joint Steering Committee meetings or upon the other Party's request by providing the Joint Steering Committee with all necessary reports in connection with its Development activities within a reasonable time, but no later than \*\*\* following such request. Gedeon Richter shall regularly inform Palatin about the actual status of the Commercialization efforts during the Joint Steering Committee meetings or upon Palatin's request by providing the Joint Steering Committee with all necessary reports in connection with the Commercialization activities within a reasonable time, but not later than \*\*\* following such request.
- 3.5 <u>Decisions of the Joint Steering Committee</u>. The Joint Steering Committee shall act by consensus. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party. The Joint Steering Committee shall strive to seek consensus in its actions and decision making process. If after reasonable discussion and good faith consideration of each Party's view on a particular matter before the Joint Steering Committee, the Joint Steering Committee is unable after a period of \*\*\* to reach consensus on such matter, then either Party may refer such matter to the Parties' respective Chief Executive Officers for good faith negotiation and resolution in accordance with Section 15.2.1; provided, however, that the Parties acknowledge and agree that (a) the purpose of the Joint Steering Committee is to facilitate the efficient Development and Commercialization of Products and (b) if either Party reasonably believes that delays caused by the foregoing resolution process would hinder or delay any Development or Commercialization activities under the Gedeon Richter Development Plan, Commercialization Plan or Palatin Development Plan or that have been committed to a Competent Authority or the FDA by a particular date, then the Parties shall reduce such time periods (including the time period contemplated by Section 15.2.1) as reasonably necessary to prevent such hindrance or delay. If the Chief Executive Officers are not able to resolve such matter within \*\*\* pursuant to Section 15.2.1 or, if applicable, the reduced period, then Gedeon Richter has the decisive vote regarding \*\*\* and Palatin has the decisive vote regarding \*\*\*. Notwithstanding the immediately preceding sentence, if the Joint Steering Committee is unable to reach consensus with respect to any matter pertaining to safety or labeling of the Product (a "Disputed Matter") and a Party (the "Invoking Party") believes in good faith that the

course of action proposed by the other Party is reasonably likely to have a material adverse effect on the Invoking Party's rights hereunder, such Invoking Party may invoke the provisions of Section 15.2 for purposes of resolving the Disputed Matter.

3.6 <u>Subcommittees</u>. From time to time, the Joint Steering Committee may establish subcommittees to oversee particular projects or activities within the scope of the authority of the Joint Steering Committee, as it deems necessary or advisable. Each subcommittee shall consist of such number of representatives of each Party as the Joint Steering Committee determines is appropriate from time to time and shall meet with such frequency as the Joint Steering Committee shall determine.

- 3.7 <u>Alliance Manager</u>. Each Party shall designate an alliance manager, who shall be responsible for the day-to-day coordination of the collaboration between the Parties and shall facilitate communication between the Parties. The Alliance Manager may but need not be one of the designated members of the Joint Steering Committee.
- 3.8 <u>Limitation on Joint Steering Committee Authority</u>. Notwithstanding the creation of the Joint Steering Committee, each Party to this Agreement shall retain the rights, powers and discretions granted to it hereunder, and the Joint Steering Committee shall not be delegated or vested with any such rights, powers or discretion unless such delegation or vesting is expressly provided for herein or the Parties expressly so agree in writing. The Joint Steering Committee shall not have the power to amend or modify this Agreement.

#### 4. DEVELOPMENT AND REGULATORY

- 4.1 Development and Regulatory Activities.
  - 4.1.1 Development and Regulatory Activities by Gedeon Richter.
- (a) Except as set forth in Section 4.1.2, Gedeon Richter shall use Commercially Reasonable Efforts to execute the Gedeon Richter Development Plan and obtain and maintain Regulatory Approval of the Product in the Territory. Gedeon Richter shall be responsible for the conduct of activities performed pursuant to the Gedeon Richter Development Plan. Without limiting the foregoing, Gedeon Richter shall \*\*\*, and \*\*\* shall occur no later than \*\*\*, with Initiation of the Pivotal Study as soon after such submission as is consistent with Commercially Reasonable Efforts. Gedeon Richter shall provide the protocol of each of its Clinical Studies and, until the completion of the Development and registration procedure in the Territory, copies of each Major regulatory submission to the Joint Steering Committee and (a) prior to commencing any such Clinical Study, allow Palatin (through its representatives on the Joint Steering Committee) to review and comment on the protocol with respect to its suitability for use in obtaining regulatory approval by the FDA, and (b) prior to submitting any such Major regulatory submission, allow Palatin (through its representatives on the Joint Steering Committee) to review and comment on the Major regulatory submission with respect to its general content and any inconsistencies with regulatory submissions outside the Territory. Palatin may review and comment on such protocols and Major regulatory submissions during the \*\*\* period after its receipt of the applicable protocol or Major regulatory submission, and Gedeon Richter shall consider in good faith any comments thereto provided by Palatin within such period; provided, however, that the Joint Steering Committee shall have the right to make all final decisions with respect to such protocols and Major regulatory submissions in the Territory. For the avoidance of doubt, the Parties agree that if approved by the Joint Steering Committee, Gedeon Richter may perform some or all of the Gedeon Richter Development Plan outside Territory.
- (b) The direct Third Party costs of the Gedeon Richter Development Plan, currently estimated at \*\*\*, will be reviewed by the Joint Steering Committee at least twice annually, with the Joint Steering Committee determining the total projected Third Party costs of the Gedeon Richter Development Plan. Until such time as \*\*\*, \*\*\* shall pay Third Party costs as they are incurred until \*\*\* has paid \*\*\* of the then currently estimated direct Third Party costs of the Gedeon Richter Development Plan, and \*\*\* shall pay Third Party costs as they are incurred until \*\*\* has paid \*\*\* of the then currently estimated direct Third Party costs. Upon the conclusion of the Gedeon Richter Development Plan, and at the discretion of the Joint Steering Committee at any review of Third Party costs of the Gedeon Richter Development Plan, the Joint Steering Committee may require that either party make additional Third Party cost payments, or make reimbursement payments to the other Party, with the objective that Palatin shall pay \*\*\*, and Gedeon Richter shall pay \*\*\*. Any Third Party costs to be reimbursed by one Party to the other Party shall be paid within thirty (30) days after the receipt of the relevant invoice issued after such Third Party costs are incurred, together with appropriate supporting documentation.

## 4.1.2 Development and Regulatory Activities By Palatin.

(a) Palatin, at its own cost, shall use Commercially Reasonable Efforts to execute the Palatin Development Plan, including the Clinical Studies specified therein or as may be amended in accordance with the provisions of this Agreement, and obtain and maintain approvals, product and/or establishment licenses, registrations or authorizations of the FDA, necessary for the commercial manufacture, use, storage, import, export, transport, commercialization or sale of the Product in the Field in the United States. Palatin shall provide the protocol of all such Clinical Studies, including the Pivotal Studies, and, until the completion of the Development and registration procedure in the Territory and in the United States, copies of each regulatory submission necessary to obtain regulatory approval by the FDA, to the Joint Steering Committee and (a) prior to commencing any such Clinical Study or Pivotal Study, allow Gedeon Richter (through its representatives on the Joint Steering Committee) to review and comment on the protocol with respect to its suitability for use in obtaining Regulatory Approval by the Competent Authorities, and (b) prior to submitting any such regulatory submission, allow Gedeon Richter (through its representatives on the Joint Steering Committee) to review and comment on the regulatory submission with respect to its general content and any inconsistencies with Major regulatory submissions in the Territory. Gedeon Richter may review and comment on such protocols and regulatory submissions during the \*\*\* period after its receipt of the applicable protocol or regulatory submission, and Palatin shall consider in good faith any comments thereto provided by Gedeon Richter within such period; provided, however, that Palatin shall have the right to make all final decisions with respect to such protocol. For the avoidance of doubt, the cost of \*\*\* shall be \*\*\*. The Parties anticipate that \*\*\*.

(b) If, in connection with Gedeon Richter's efforts to obtain Regulatory Approval of the Product by the Competent Authorities, Gedeon Richter, using Commercially Reasonable Efforts, completes \*\*\* which has met its primary endpoints, and (i) the EMA or the reference member state (RMS) does not grant Marketing Authorization based on the above \*\*\* and the \*\*\* or (ii) the Joint Steering Committee decides that \*\*\* is necessary for Gedeon Richter to obtain the Regulatory Approval in Territory, then \*\*\* such \*\*\*, which \*\*\* will be conducted by \*\*\* in the United States or the EU, at Gedeon Richter's option. \*\*\* shall provide the protocol of such \*\*\* to the Joint Steering

Committee and, prior to commencing such \*\*\*, allow \*\*\* (through its representatives on the Joint Steering Committee) to review and comment on the protocol with respect to its suitability for use in obtaining Regulatory Approval by the Competent Authorities or regulatory approval by the FDA. \*\*\* may review and comment on such protocol during the \*\*\* period after its receipt of the protocol, and \*\*\* shall consider in good faith any comments thereto provided by \*\*\* within such period; provided, however, that the Joint Steering Committee shall have the right to make all final decisions with respect to such protocol. \*\*\*.

(c) If the Initiation of at least one Pivotal Study contemplated by Section 4.1.2(a) does not occur on or before \*\*\*, then, as Gedeon Richter's sole remedy:

- (i) Gedeon Richter may by written notice to Palatin terminate this Agreement. If Gedeon Richter terminates this Agreement pursuant to this Section 4.1.2(c)(i), then (A) the License shall immediately terminate, (B) Gedeon Richter shall, within \*\*\* following the effective date of the termination, return to Palatin all Palatin Know-How and, at Palatin's option, transfer, assign, convey and deliver to Palatin all Gedeon Richter Know-How, and (C) Palatin shall, within \*\*\* after Gedeon Richter fulfills its obligations pursuant to Section 4.1.2(c)(i)(B), reimburse Gedeon Richter \*\*\* (representing \*\*\*% of the sum of the \*\*\* and the option fee paid pursuant to that certain Option to Negotiate an Exclusive License, dated \*\*\*, between Palatin and Gedeon Richter, as amended). Palatin shall reimburse Gedeon Richter for all reasonable out-of-pocket costs actually incurred by Gedeon Richter in connection with the transfer, assignment, conveyance and delivery of the Gedeon Richter Know How pursuant to Section 4.2.1(c)(1)(B); or
  - (ii) Gedeon Richter may elect to maintain its License, provided that \*\*\*.
- (d) Palatin undertakes to perform all CMC Development activities, including the necessary technical design and Development of the relevant autoinjector, necessary for Gedeon Richter to obtain and maintain the Regulatory Approval of the Product in the Territory; provided, however that if Gedeon Richter assumes responsibility for conducting manufacturing activities pursuant to Section 6.3, then Gedeon Richter shall also assume responsibility for CMC Development activities to the extent relating thereto.
- (e) Upon Gedeon Richter's request and if available at Palatin, Palatin shall transfer the relevant analytical methods necessary for the performance of the Gedeon Richter Development Plan, to Gedeon Richter, free of charge.
- 4.1.3 <u>Further Development Activities</u>. The Parties, through the Joint Steering Committee, shall negotiate in good faith to amend the Gedeon Richter Development Plan and the Palatin Development Plan from time to time for the conduct of additional development activities. Should a Party desire to conduct further development studies for the Product, including, without limitation, post-marketing studies, the Parties shall discuss the possible conduct of such development activities. Each Party shall obtain the Joint Steering Committee's consent before conducting such further development studies for the Product, such consent not to be unreasonably withheld. Unless otherwise agreed, and except to the extent that such further development studies are included in the Gedeon Richter Development Plan and to be paid, in part, by Palatin pursuant to Section 4.1.1(b), \*\*\* shall \*\*\* costs in connection with such further development studies.

  Notwithstanding the foregoing, the Parties agree that in the case of any preclinical or clinical study (including the post-marketing studies) imposed or requested by the Competent Authority (in the case of Gedeon Richter) or FDA (in the case of Palatin), each Party shall be free to perform, at its own cost, such study without the Joint Steering Committee's consent.
- 4.1.4 <u>Material Transfer</u>. To facilitate the Development activities hereunder, either Party may provide to the other Party certain biological materials, chemical compounds such as the active pharmaceutical ingredient or its formulated forms, development and regulatory materials or any other materials necessary for obtaining Regulatory Approval in the Territory, owned by or licensed by a Third Party to the supplying Party for use by the other Party in furtherance of such Development activities (such materials or compounds provided hereunder are referred to, collectively, as "Materials"), provided that any licensed Materials may only be provided as permitted under the relevant license agreement. Except as otherwise provided under this Agreement, all such Materials delivered to the other Party shall remain the sole property of the supplying Party, shall be used in furtherance of the Development activities and solely under the control of the other Party (or its Affiliates), shall not be used or delivered to or for the benefit of any Third Party without the prior written consent of the supplying Party, and shall not be used in research or testing involving human subjects, unless expressly agreed. The Materials supplied under this Section 4.1.4 are supplied "as is" and must be used with prudence and appropriate caution in any experimental work, since not all of their characteristics may be known.

## 4.2 Specific Regulatory Responsibilities.

- 4.2.1 <u>Gedeon Richter's Responsibilities</u>. Gedeon Richter or its designated representatives or its Sublicensee(s) will be the applicant and the holder of the marketing authorization in all countries in the Territory, and Gedeon Richter will be the responsible Party to submit the Marketing Authorization Application and shall use Commercially Reasonable Efforts to carry out the registration procedures necessary to obtain Regulatory Approvals in the Territory. Subject to Section 4.1.1 and the approval of the Joint Steering Committee, \*\*\*. During the term of this Agreement, Gedeon Richter shall, at its own cost, execute all updates of the Dossier. Gedeon Richter shall notify Palatin of any necessary update to the Dossier promptly after becoming aware of the need for such update. Nothing in this Section 4.2.1 is intended to limit Gedeon Richter's obligations under Section 4.1.1 with respect to obtaining and maintaining Regulatory Approval of the Product in the Territory or Gedeon Richter's obligations under Section 4.3.3 with respect to the exchange of information relating to its Development and regulatory activities under this Agreement.
- 4.2.2 <u>Palatin's Responsibilities</u>. Palatin will be the responsible Party for submitting, or causing to be submitted, the NDA and shall use Commercially Reasonable Efforts to obtain regulatory approval by the FDA. To the extent such information is in Palatin's possession or under its control on the Effective Date or will be in Palatin's possession after the Effective Date, and subject to Section 4.1.2 and any applicable contractual obligations requiring confidentiality, Palatin shall, at its own cost, be responsible for (a) preparing and providing Gedeon Richter with the necessary administrative, pre-clinical, clinical and CMC part of the Dossier in accordance with the prevailing European Union Guidelines ("Notice to Applicants") to support, to obtain and to maintain the Regulatory Approvals for the Product in the Field in the Territory, including the full eCTD and any other relevant data, information, results, reports and databases in any format, (b) within \*\*\* after Gedeon Richter's written request, providing any additional Information, samples and supporting documentation that is required for obtaining the Regulatory Approval(s) and price approvals in the Territory. In addition, upon Palatin submitting a U.S. NDA Data Package to the FDA, Palatin shall provide the U.S. NDA Data Package to Gedeon Richter within \*\*\* after the U.S. NDA submission, which is anticipated to be no later than \*\*\*. Upon Gedeon Richter's request, Palatin shall use Commercially Reasonable Efforts to assist Gedeon

Richter in answering any questions raised by the Competent Authorities in connection with Gedeon Richter's efforts to obtain and maintain the Regulatory Approvals. Palatin shall provide reasonable assistance to Gedeon Richter in connection with the preparation and finalization of the Dossier. Palatin shall notify Gedeon Richter of any necessary update to the Dossier promptly after becoming aware of the need for such update and shall cooperate with Gedeon Richter and timely provide to Gedeon Richter any available information necessary to implement any required changes to the Dossier. Nothing in this Section 4.2.2 is intended to limit Palatin's obligations under Section 4.3.3 with respect to the exchange of information relating to its development activities under this Agreement.

- 4.3.1 Compliance with the Gedeon Richter Development Plan, the Palatin Development Plan and Applicable Laws All Development and regulatory activities in connection with the clinical development programs conducted to obtain and maintain Regulatory Approval for the Product in the Territory shall be conducted by and on behalf of Gedeon Richter in accordance with the Gedeon Richter Development Plan and the other provisions of this Agreement, and by and on behalf of Palatin in accordance with the Palatin Development Plan and the other provisions of this Agreement. Each Party shall conduct those activities for which it is the responsible Party under the Gedeon Richter Development Plan or Palatin Development Plan and the other provisions of this Agreement, as applicable, in compliance in all material respects with all applicable laws and in accordance with GLP and GCP and GVP (when applicable) under the applicable laws of the country in which such activities are conducted.
- 4.3.2 <u>Diligence</u>. Gedeon Richter shall use Commercially Reasonable Efforts to conduct and complete the studies and activities assigned to it in the Gedeon Richter Development Plan and the other provisions of this Agreement in order to achieve the goals of the Gedeon Richter Development Plan in accordance with the timelines accepted by the Joint Committee. Palatin shall use Commercially Reasonable Efforts to conduct and complete the studies and activities assigned to it in the Palatin Development Plan and the other provisions of this Agreement in order to achieve the goals of the Palatin Development Plan in accordance with the timelines accepted by the Joint Committee.
- 4.3.3 Information Regarding Development Activities. Each Party shall maintain records, in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work done and results achieved by or on behalf of such Party in the performance of its development activities under this Agreement. Each Party shall keep the Joint Steering Committee appropriately informed of the status of its clinical development program and other activities conducted under the Gedeon Richter Development Plan, the Palatin Development Plan and the other provisions of this Agreement, as applicable, and its other development activities with respect to the Product in the Field. Without limiting the foregoing, each Party shall, on a \*\*\* basis (or, if sooner, promptly upon request by the Joint Steering Committee), provide the Joint Steering Committee with summaries of data and results and all supporting data and results generated or obtained in the course of such Party's performance of studies and activities under the Gedeon Richter Development Plan and the Palatin Development Plan, and the other provisions of this Agreement, as applicable. Each Party shares any Information with the other Party on request. Upon reasonable prior written notice, each Party shall have the right to inspect records and notebooks reflecting the work done and results achieved by or on behalf of the other Party in the performance of its development activities with respect to the Product in the Field pursuant to either the Gedeon Richter Development Plan or the Palatin Development Plan and the other provisions of this Agreement, as applicable. The Parties may use information exchanged pursuant to this Section 4.3.3 for any purpose in connection with the Development and Commercialization of Products in the Field in the Territory (in the case of Gedeon Richter) and outside the Field in the Territory and outside the Territory (in the case of Palatin).
- 4.4 Pharmacovigilance and Risk Management. The Parties shall handle safety information, including adverse events occurring or having occurred in connection with the use of the Product, in accordance with applicable laws and the requirements of GVP, the Competent Authorities, the FDA and other relevant regulatory authorities, as applicable. The Parties shall exchange all relevant safety information, including information concerning adverse events occurring or having occurred in connection with the use of the Product and information obtained from any kind of investigation for reporting purposes such as, for non-limiting example, periodic safety reports. No later than \*\*\* before the projected launch of the Product in the first country of the Territory, the Parties shall execute a separate agreement relating to safety matters and defining the pharmacovigilance and risk management obligations of the Parties (including, but not limited to, procedures for the exchange of safety information and the roles and responsibilities of the Parties in connection with the maintenance of a global safety database for the Product). In the absence of such separate agreement, either Party may at any time and from time to time refer material safety matters to the Joint Steering Committee for consideration and resolution.
- 4.5 Regulatory Communications. Both Parties shall timely inform the Joint Steering Committee of all of their scheduled meetings with the Competent Authorities (in the case of Gedeon Richter) and the FDA (in the case of Palatin) and provide the Joint Steering Committee with summaries of such meeting with the Competent Authorities or FDA promptly after each meeting. In addition, the Parties shall promptly provide the Joint Steering Committee with copies of all written communications and a summary of material oral discussions with the Competent Authorities (in the case of Gedeon Richter) and the FDA (in the case of Palatin) with respect to the Product. In addition to the information required to be provided to the Joint Steering Committee in other provisions of this Agreement, both Parties shall timely provide the Joint Steering Committee with summaries of any of their communications and correspondence with the Competent Authorities, FDA or other applicable regulatory authorities in the Territory or outside the Territory with respect to the Product. The Parties may use information exchanged pursuant to this Section 4.5 for any purpose in connection with the Development and Commercialization of Products in the Field in the Territory (in the case of Gedeon Richter) and outside the Field in the Territory and outside the Territory (in the case of Palatin).
- 4.6 Regulatory Costs. All costs to be incurred in connection with the registration of the Product (including but not limited to filing fees, registration costs, storage and transportation costs and other out-of pocket costs relating to the receipt of all regulatory and marketing approvals) in the Territory will be borne by \*\*\*. In the event such costs are initially incurred at \*\*\* due to any reason, \*\*\* will reimburse them in the same currency as it was paid by \*\*\* no later than \*\*\* from the receipt of \*\*\* respective invoice. \*\*\* shall attach to its invoice(s) all available supportive documents.

- 5.1 <u>Commercialization of the Product</u>. The Parties agree that Gedeon Richter or its Sublicensee(s) will exclusively Commercialize the Product in the Territory under Gedeon Richter's commercial name and trademark. Gedeon Richter will use Commercially Reasonable Efforts to launch the Product within the shortest period of time in \*\*\* after obtaining the Regulatory Approval, and in any event will launch the Product in \*\*\* no later than \*\*\* after the receipt of the Regulatory Approval and price approval or price reimbursement (if applicable) in the respective country.
- 5.2 <u>Commercialization Plan</u>. Within \*\*\* after the initial regulatory filing in, or otherwise applicable to, any of the \*\*\*, Gedeon Richter shall prepare a commercialization plan for \*\*\* outlining its proposed premarketing and marketing activities, including anticipated investments, and expected sales levels relating to Product (the "Commercialization Plan"). The Commercialization Plan will be reviewed and approved by the Joint Steering Committee.

5.3 <u>Diligence</u>. Gedeon Richter agrees to use Commercially Reasonable Efforts to diligently Commercialize the Product in the Field in the Territory and obtain such approvals as may be necessary for the sale of the Product. Gedeon Richter's efforts shall be comparable to those efforts Gedeon Richter makes with respect to its other products of market potential, stage of development and patent protection.

#### 6. SUPPLY FOR DEVELOPMENT AND COMMERCIAL SUPPLY

- 6.1 Subject to the terms of this Agreement, during the term of this Agreement and until Palatin supplies Product under the Supply Agreement for Development and Commercial Supply Agreement, Palatin shall manufacture in accordance with GMP and supply the Investigational Product and if necessary the relevant placebo product or the active pharmaceutical ingredient of the Product for use by Gedeon Richter in connection with the research and Development of the Product in the Field in the Territory in accordance with the Gedeon Richter Development Plan and to carry out all activities necessary for obtaining and maintaining the Regulatory Approval. Palatin shall, by itself or through its Third Party contract manufacturers, supply to Gedeon Richter (or its Affiliates or Sublicensees) all quantities of Investigational Product (packaged or prepackaged) required by Gedeon Richter (or its Affiliates or Sublicensees) for the Development of the Product in the Field in the Territory. All Product supplied to Gedeon Richter pursuant to this Article 6 shall be manufactured in accordance with GMP and used exclusively for conducting the studies and activities specified in the Gedeon Richter Development Plan. The price of such Investigational Product shall be \*\*\*\*. Palatin shall issue the relevant invoice for such payment which shall be paid by Gedeon Richter no later than \*\*\* from the receipt of Palatin's respective invoice. Palatin shall attach to its invoice(s) appropriate supporting documentation.
- **6.2** The Parties agree to execute a separate supply agreement for the supply of the Investigational Product or any material necessary for the Development of the Product in the Field in the Territory (the "Supply Agreement for Development"). All other supply, including commercial supply, of the Product shall be as set forth in a separate commercial supply agreement (the "Commercial Supply Agreement").
- **6.3** The Commercial Supply Agreement shall provide, inter alia, that if Palatin determines to retain a Third Party, other than the Third Parties specified in Exhibit VII hereto or any Third Party retained by Palatin to provide an alternative source supplier for the Third Parties specified in Exhibit VII, for the purpose of manufacturing the Product for distribution in the Field in the Territory, then Palatin shall provide written notice of the same to Gedeon Richter (the "Manufacture Offer Notice"). If, within \*\*\* after its receipt of the Manufacture Offer Notice, Gedeon Richter indicates by written notice \*\*\*, a mutually acceptable term sheet for amending or revising the Commercial Supply Agreement to provide for \*\*\*. If the Parties are not able to reach agreement on and do not execute a term sheet with respect to the \*\*\* within such \*\*\* period, Palatin shall be free to \*\*\* without further obligation to Gedeon Richter.

## 7. UPFRONT AND MILESTONE PAYMENTS

- 7.1 Within \*\*\* following the receipt of the relevant invoice issued by Palatin on the Effective Date of this Agreement, Gedeon Richter shall pay to Palatin 6,730,771 EUR (six million seven hundred and thirty thousand seven hundred and seventy-one euros) (the "Upfront Payment").
  - 7.2 During the term of this Agreement, Gedeon Richter shall pay to Palatin the following milestone payments:

Milestones	Milestone Payments:	
Upon Initiation of first Phase III Study or Pivotal Study by Palatin	2,500,000 EUR (two million five hundred thousand euros)	
pursuant to Section 4.1.2(a)		
Upon ***	***	
Upon ***	An amount equal to ***	
Upon ***	For each ***, an amount *** equal to ***	
Upon the end of the first such year of Commercialization of the Product during which the aggregate Net Sales (from inception of Commercialization) exceed ***. This is a one-time, sales-related milestone based on cumulative Net Sales.	An amount equal to ***	
Upon the end of the first such year of Commercialization of the Product during which the aggregate Net Sales (from inception of Commercialization) exceed ***. This is a one-time, sales-related milestone based on cumulative Net Sales.	An amount equal to ***	
Upon the end of the first such year of Commercialization of the Product during which the Net Sales exceed *** for the first time in a single year. This is a one-time, sales-related milestone payment based on annual Net Sales.	***	
Upon the end of the first such year of Commercialization of the Product during which the Net Sales exceed *** for the first time in a single year. This is a one-time, sales-related milestone payment based on annual Net Sales.	***	
Upon the end of the first such year of Commercialization of the Product during which the Net Sales exceed *** for the first time in a single year. This is a one-time, sales-related milestone payment based on annual Net Sales.	***	

Upon the end of the first such year of Commercialization of the Product during which the Net Sales exceed \*\*\* for the first time in a single year. This is a one-time, sales-related milestone payment based on annual Net Sales.

Total \*\*\*

#### 8. ROYALTIES

- 8.1 Royalty on Net Sales. On a \*\*\*, Gedeon Richter shall pay to Palatin royalties on the Net Sales of Product in each country in the Territory \*\*\*:
  - (i) \*\*\*;
  - (ii) the date that is the \*\*\* of the Effective Date; and
  - (iii) the date that is the \*\*\* of the First Commercial Sale.
- 8.2 <u>Royalty Rate</u>. The royalty rate payable by Gedeon Richter on Net Sales of the Product in the Territory by Gedeon Richter, its Affiliates and its Sublicensees shall be \*\*\*. Sales between Gedeon Richter, its Affiliates and its Sublicensees shall not be counted as Net Sales for purposes of calculating the royalties payable hereunder.

In case the Joint Steering Committee decides that \*\*\*, then the royalty rate payable to Palatin according to this section shall be \*\*\* percent (\*\*\*%) instead of \*\*\* percent (\*\*\*%) for the remaining term of this Agreement.

- 8.3 Royalty Rate Reduction. Royalty rates with regard to the Product will be reduced by \*\*\* percent (\*\*\* %), on a \*\*\*, should any Third Party market in any country in the Territory during the term of this Agreement generic product(s) that are directly competitive with the Product if and for so long as (a) such generic product(s) has in such country an approved public price at least \*\*\* percent (\*\*\*%) less than the public price of the Product and (b) sales of such generic product(s) in such country constitute in the immediately preceding \*\*\* period \*\*\* percent (\*\*\*%) of the Product's market share in volume as evidenced by IMS data provided by Gedeon Richter. The reduced royalty rates will apply to Net Sales of the Product in the applicable country effective as of the first day of the next calendar quarter after Gedeon Richter provides written notice of the royalty rate reduction to Palatin and supporting documentation reasonably satisfactory to Palatin demonstrating that the conditions described in this Section 8.3 have been satisfied.
- 8.4 <u>Royalties Payable to Third Parties</u> If there are any royalties to be paid by Palatin to any Third Party licensors, Palatin shall be liable for the payment of such royalties, and Palatin's payment of such royalties shall not affect the amounts otherwise due or payable by Gedeon Richter hereunder.

#### 9. PAYMENTS

- 9.1 <u>Royalty Reports and Payments</u>. Gedeon Richter shall make royalty payments to Palatin on a quarterly basis within \*\*\* after the end of each calendar quarter in which Net Sales occurred. A report summarizing the Net Sales of each Product during the relevant quarter on a country-by-country basis shall be delivered to Palatin within \*\*\* following the end of each calendar quarter for which royalties are due.
- 9.2 <u>Milestone Payments</u>. Gedeon Richter will make milestone payments to Palatin within \*\*\* after the receipt of the relevant invoice of Palatin issued after the respective milestone has been reached.
- 9.3 <u>Payments Interest</u>. Any payments due under this Agreement shall be due on such date as specified in this Agreement and, in the event such date is not a Business Day, then the next succeeding Business Day. Based on any failure of Gedeon Richter to make a payment within \*\*\* after the due date, Gedeon Richter shall pay computed interest (the interest period commences on the due date and ends on the payment date) to Palatin at a rate per annum equal to the EUR LIBOR or USD LIBOR, as the case may be (according to the underlying payment due), for one month quoted on the due date by the European Central Bank plus a premium of \*\*\* percent (\*\*\*%). The interest rate shall be adjusted monthly and interest shall be compounded monthly in arrears. In addition, interest shall be computed on the basis of a 360 day year actual days elapsed, and shall be due and payable on the tender of the underlying principal payment.
- 9.4 <u>Taxes</u>. If laws or regulations require that taxes be withheld, Gedeon Richter will (a) deduct those taxes from the remittable payment, (b) timely pay the taxes to the proper taxing authority, and (c) send proof of payment to Palatin within thirty (30) days of receipt of confirmation of payment from the relevant taxing authority. Gedeon Richter agrees to make all lawful and reasonable efforts to minimize such taxes to Palatin. If Gedeon Richter is so required then Palatin and Gedeon Richter shall co-operate in all respects and take all reasonable steps to lawfully avoid the making of any such deductions.
- 9.5 <u>Calculation of Royalties and Sales-Related Milestone Payments</u> Gedeon Richter will calculate Net Sales on a monthly basis based on the aggregate Net Sales in all countries in the Territory \*\*\*. The conversion of Net Sales that occur in currencies other than HUF will be made by \*\*\*, as approved by Gedeon Richter's principal auditor, consistently applied. For purposes of calculating the amount of royalties payable pursuant to Article 8 and determining whether sales-related milestones have been achieved, Net Sales, \*\*\*; provided, however, \*\*\*.

9.6 <u>Payment Currency</u>. All payments made pursuant to this Agreement, including the Upfront Payment, Milestone Payments and all royalties payable pursuant to Article 8, will be paid to Palatin in EUR. All payments shall be paid by wire transfer of immediately available funds to an account at a commercial bank designated by Palatin at least ten (10) Business Days before payment is due.

#### 9.7 Records of Revenues and Expenses.

9.7.1 Gedeon Richter shall maintain complete and accurate records which are relevant to the revenues on a country-by-country basis under this Agreement, and such records shall be open during reasonable business hours for a period of \*\*\* from creation of individual records for examination at Palatin's expense and not more often than \*\*\* by a certified public accountant selected by Palatin or Palatin's internal accountants, unless Gedeon Richter objects to the use of such internal accountants, for the sole purpose of verifying for Palatin the correctness of calculations and classifications of such revenues under this Agreement. Palatin shall bear its own costs related to such audit; provided, that for any underpayments greater than \*\*\* percent (\*\*\*%) by Gedeon Richter, Gedeon Richter shall pay Palatin the amount of underpayment, interest as provided for in Section 9.3 from the time the amount was due and Palatin's out-of-pocket expenses. For any underpayments less than \*\*\* percent (\*\*\*%) by Gedeon Richter found under this Section 9.7.1, Gedeon Richter shall pay Palatin the amount of such underpayment. If Gedeon Richter shall pay any underpayment even it is over \*\*\* percent (\*\*\* %) before such examination to be made by Palatin, no interest or no other payments will be made consequently. Any overpayments by Gedeon Richter will, at Palatin's option, be refunded to Gedeon Richter or credited to future royalties. Any records or accounting information received from Gedeon Richter shall be confidential information for purposes of Section 10.1. Results of any such audit shall be provided to both Parties and shall be confidential information for purposes of Section 10.1.

9.7.2 If there is a dispute between the Parties following any audit performed pursuant to Section 9.7.1, either Party may refer the issue (an "Audit Disagreement") to an independent certified public accountant for resolution. In the event an Audit Disagreement is submitted for resolution by either Party, the Parties shall comply with the following procedures: (a) the Party submitting the Audit Disagreement for resolution shall provide written notice to the other Party that it is invoking the procedures of this Section 9.7.2; (b) within thirty (30) Business Days of the giving of such notice, the Parties shall jointly select a recognized international accounting firm to act as an independent expert to resolve such Audit Disagreement; (c) the Audit Disagreement submitted for resolution shall be described by the Parties to the independent expert, which description may be in written or oral form, within ten (10) Business Days of the selection of such independent expert; (d) the independent expert shall render a decision on the matter as soon as practicable; (e) the decision of the independent expert shall be final and binding unless such Audit Disagreement involves alleged fraud, breach of this Agreement or construction or interpretation of any of the terms or conditions hereof; and (f) all fees and expenses of the independent expert, including any Third Party support staff or other costs incurred with respect to carrying out the procedures specified at the direction of the independent expert in connection with such Audit Disagreement, shall be borne by each Party in inverse proportion to the disputed amounts awarded to the Party by the independent expert through such decision (e.g., Palatin disputes \$100 and the independent expert awards Palatin \$60, then Palatin pays forty percent (40%) and Gedeon Richter pays sixty percent (60%) of the independent expert's costs).

#### 10. CONFIDENTIALITY

- 10.1 <u>Confidential Information</u>. Except as expressly provided herein, the Parties agree that, for the term of this Agreement and for \*\*\* thereafter, the receiving Party shall keep completely confidential and shall not publish or otherwise disclose and shall not use for any purpose except for the purposes contemplated by this Agreement any Information furnished to it by the disclosing Party hereto pursuant to this Agreement, except that to the extent that it can be established by the receiving Party by competent proof that such Information:
- 10.1.1 is or becomes public or available to the general public otherwise than through the act or default of the receiving Party;
- 10.1.2 is obtained by the receiving Party from a Third Party who is lawfully in possession of such Information and is not subject to an obligation of confidentiality or non-use owed to the disclosing Party or others;
- 10.1.3 is previously known to the receiving Party prior to disclosure to the receiving Party by the disclosing Party under this Agreement or otherwise, as shown by written evidence, and is not obtained or derived directly or indirectly from Information obtained from the disclosing Party;
- 10.1.4 is disclosed by the receiving Party pursuant to the requirement of law, provided that the receiving Party has complied with the provisions set forth in Section 10.3; or
- 10.1.5 is independently developed by the receiving Party without the use of or reliance on any Information provided by the disclosing Party hereunder, as shown by contemporaneous written evidence.
- 10.2 <u>Public Domain</u>. For the purposes of this Agreement, specific information disclosed as part of the Information shall not be deemed to be in the public domain or in the prior possession of the receiving Party merely because it is embraced by more general information in the public domain or by more general information in the prior possession of the receiving Party.
- 10.3 <u>Legal Disclosure</u>. If the receiving Party becomes legally required to disclose any Information provided by the disclosing Party, the receiving Party will give the disclosing Party prompt notice of such fact so that the disclosing Party may obtain a protective order or other appropriate remedy concerning such disclosure and/or waive compliance with the non-disclosure provision of this Agreement. The receiving

Party will reasonably cooperate with the disclosing Party in connection with the disclosing Party's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude disclosure or the disclosing Party waives such compliance, the receiving Party will make such disclosure only to the extent that such disclosure is legally required and will use its reasonable efforts to have confidential treatment accorded to the disclosed Information.

- 10.4 <u>Permitted Use and Disclosures</u>. Each Party hereto may use or disclose Information disclosed to it by the other Party to the extent such use or disclosure is reasonably necessary in complying with applicable governmental or regulatory regulations or otherwise submitting information to tax or other governmental authorities, conducting preclinical or clinical development, or otherwise exercising its rights hereunder. Provided that, if a Party is required to make any such disclosure of another Party's confidential Information, other than pursuant to a confidentiality agreement, it will give reasonable advance notice to the latter Party of such disclosure and, save to the extent inappropriate in the case of patent applications, will use its reasonable efforts to secure confidential treatment of such Information prior to its disclosure (whether through protective orders or otherwise).
- 10.5 <u>Public Disclosure</u>. Except as otherwise required by law (including regulations promulgated by the US Securities and Exchange Commission) or the rules of Hungary's Stock Exchange or the NYSE MKT, neither Party shall issue a press release or make any other public disclosure of the terms of this Agreement without the prior approval of the other Party. Each Party shall submit any such press release or public disclosure to the other Party for review and approval prior to public disclosure, which approval shall not be unreasonably withheld. If such other Party does not respond within thirty (30) days after receipt, the press release or public disclosure shall be deemed approved in the form originally proposed. Notwithstanding the foregoing, if a public disclosure is required by law (a "Required Disclosure"), including without limitation in a filing with the US Securities and Exchange Commission or in accordance with the rules of Hungary's Stock Exchange or the NYSE MKT, the disclosing Party shall provide copies of the Required Disclosure to the non-disclosing Party reasonably in advance of such filing or other disclosure for the non-disclosing Party's review and comment (but not approval). Each Party shall consider in good faith any comments provided by the other Party with respect to the content of the Required Disclosure, including with respect to the redaction of this Agreement and any other agreement that is to be filed or otherwise publicly disclosed in connection with the Required Disclosure.
- 10.6 <u>Scientific Publication</u>. In the event that either Party is required or obliged or desires to make any scientific publication in a scientific journal or at the conference in any academic society including Information obtained by itself during the performance of Gedeon Richter Development Plan or Palatin Development Plan and the other provisions of this Agreement, as applicable, such Party shall submit to the other Party the full text of such scientific publication at least thirty (30) working days prior to such submission for review and approval. The Parties shall discuss in good faith whether such publication should be made in consideration of the advantages and disadvantages arising from such publication. For the avoidance of doubt, neither Party shall be allowed to make any publication without the other Party's consent, which shall not be unreasonable withheld, it being expressly understood that each Party shall at all times be entitled to withhold its consent in the event such Party reasonably considers the relevant publication to prejudice its interests or rights under this Agreement.
- 10.7 <u>Confidential Terms</u>. Except as expressly provided herein, each Party agrees not to disclose any terms of this Agreement to any Third Party without the consent of the other Party; except that disclosures may be made as required by securities or other applicable laws, or to actual or prospective investors or corporate partners, or to a Party's accountants, attorneys and other professional advisors.
  - 10.8 Survival. This Article 10 will survive expiry or termination of this Agreement for any reason.

## 11. REPRESENTATIONS, WARRANTIES AND COVENANTS

- 11.1 <u>Mutual Representations and Warranties</u>. Each Party hereby represents and warrants to the other Party as of the Effective Date as follows:
- 11.1.1 <u>Due Organization</u>. Such Party is a corporation duly organized, validly existing and in good standing under the laws of the state or country of its incorporation (as set forth in the recitals of this Agreement), and is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business or the ownership of its properties requires such qualification and failure to have such would prevent it from performing its obligations under this Agreement. Such Party has all requisite corporate power and authorization to own, lease and operate all assets and properties necessary to carry on its business as now being conducted.
- 11.1.2 <u>Due Execution</u>. The execution, delivery and performance by such Party of this Agreement have been duly authorized by all necessary corporate action and do not and will not (i) require any consent or approval of its stockholders or (ii) violate any provision of any law, rule, regulation, order, writ, judgment, injunction, decree, determination or award presently in effect having applicability to it or any provision of its charter or bylaws.
- 11.1.3 <u>Binding Agreement</u>. This Agreement, when executed and delivered by both Parties, is a legal, valid and binding obligation of such Party, enforceable against it in accordance with the terms and conditions hereof.
- 11.1.4 <u>Authorization</u>. Such Party has obtained all authorizations, consents and approvals, governmental or otherwise, necessary for such Party to grant the rights and licenses granted by such Party under this Agreement, and to otherwise perform such Party's obligations under this Agreement.
- 11.1.5 <u>Conflicting Agreements</u>. The execution, delivery and performance of this Agreement (i) are not prohibited or limited by, and will not result in the breach of or a default under, any provision of the certificate or articles of incorporation or bylaws of such Party; (ii) do not conflict with any law applicable to such Party; and (iii) do not conflict with, result in a breach of, constitute a default under, any material agreement binding on Palatin and/or Gedeon Richter or any applicable order, writ, injunction or decree of any regulatory authority to which Palatin and/or Gedeon Richter is a party or by which Palatin and/or Gedeon Richter is bound. Such Party has not previously granted any rights in conflict with or that otherwise interfere with the rights and licenses granted herein. As of the Effective Date there are no existing agreements, options, commitments or rights with, of or to any person or entity to acquire or obtain any rights with respect to such Party's

- 11.1.6 <u>False Statement</u>. Neither such Party, nor any officer or employee of such Party, has knowingly made an untrue statement of a material fact to any regulatory authority with respect to the Product, or has knowingly failed to disclose a material fact required to be disclosed to any regulatory authority with respect to the Product.
- 11.1.7 <u>Litigation</u>. There is no action pending or, to such Party's best knowledge, threatened in writing, directly or indirectly involving such Party that would prohibit, hinder, materially delay or otherwise impair its ability to perform its obligations hereunder or otherwise affect the legality, validity or enforceability of this Agreement, or prevent or materially delay the execution of this Agreement.
- 11.2 <u>Palatin's Additional Representations and Warranties</u>. Palatin represents and warrants to Gedeon Richter as of the Effective Date as follows:
- 11.2.1 <u>Title</u>. Palatin owns or controls all right, title and interest in and to the intellectual property rights of Palatin, including the Palatin Know-How and Palatin Patents, to the extent licensed to Gedeon Richter under this Agreement. Palatin has the right to grant to Gedeon Richter all of the licenses and other rights with respect to Palatin's intellectual property rights granted to Gedeon Richter under this Agreement free and clear of all encumbrances or claims of any kind.
- 11.2.2 No Conflicts. Palatin has not entered into any agreement or granted any rights with respect to the License that are inconsistent with the rights granted to Gedeon Richter under this Agreement or which would limit or encumber Gedeon Richter's ability to exercise the rights and licenses granted to Gedeon Richter under this Agreement.
- 11.2.3 <u>Infringement</u>. To Palatin's best knowledge, the practice by Gedeon Richter of any right granted herein will not infringe any valid patent.
- 11.2.4 <u>Maintenance</u>. All application and renewal fees and other steps required for the maintenance or protection of the Palatin Patents in the Territory have been paid on time or taken.
- 11.2.5 <u>Disputes</u>. There are no claims, challenges, disputes or proceedings, now pending or threatened, with respect to ownership, validity or use of the Palatin Patents in the Field in the Territory.

#### 11.3 Covenants.

- 11.3.1 <u>Inconsistent Rights.</u> Each Party hereby covenants to the other that during the Term, it will not grant, any rights in conflict with or that would otherwise interfere with the rights and licenses granted herein. Throughout the Term, neither Party shall cause existing agreements, options, commitments or rights with, of or to any person or entity to acquire or obtain any rights with respect to such Party's intellectual property in conflict with the rights and licenses granted herein.
- 11.3.2 <u>Compliance with Law.</u> Each Party shall comply, and shall cause its Affiliates, Sublicensees, contractors and consultants to comply, with all applicable laws in performing their respective obligations and exercising their respective rights hereunder.
- 11.3.3 <u>Competitive Products</u>. Without the prior written consent of Palatin Gedeon Richter shall not engage, directly or indirectly, in \*\*\*. For the avoidance of doubt, this does not include \*\*\*.

## 12. INTELLECTUAL PROPERTY AND OWNERSHIP

#### 12.1 Ownership.

- 12.1.1 As between the Parties, Palatin shall retain all right, title and interest in and to the Palatin Know-How. Any invention, whether patentable or not, derived from the Palatin Know-How shall be Palatin's sole property.
- 12.1.2 As between the Parties, Gedeon Richter shall retain all right, title and interest in and to the Gedeon Richter Know-How. Any invention, whether patentable or not, derived from such Gedeon Richter Know-How shall be Gedeon Richter's sole property. Gedeon Richter grants to Palatin \*\*\* in connection with the Development and Commercialization of Products \*\*\*, subject to all terms and conditions of this Agreement.

## 12.2 Patent Rights.

12.2.1 <u>Patent Prosecution - Palatin Patents</u>. \*\*\* shall be responsible, at \*\*\* expense, for preparing, filing, prosecuting and maintaining (including conducting any interferences, re-examinations, reissues and oppositions) the Palatin Patents in Territory, by itself or with Third Parties. \*\*\* will consult with \*\*\* in all matters related to the Palatin Patents that are relevant to the Product in the Field. \*\*\* shall implement all requests made by the Joint Steering Committee with regard to the preparation, filing, prosecution and/or maintenance of such Palatin Patents, including any extension of the Patent protection in the Territory. In case of any opposition or nullification procedure initiated by any Third Party in the Territory, \*\*\* shall consult with \*\*\* and shall take all actions to prevent or terminate such procedure.

12.2.2 <u>Infringement Claims against Gedeon Richter</u>. \*\*\* shall give a written notice of any claim or threatened by a Third Party for infringement of such Third Party patents by the Product, or its use in the Field of Use in the Territory ("Patent Infringement Claim") within \*\*\* of the first knowledge of the claim or threatened claim. \*\*\* shall have the right to take actions and to defend with respect to such Patent Infringement Claim, provided that \*\*\* shall provide all its reasonable assistance to \*\*\* in all actions brought against Palatin and/or Gedeon Richter by Third Parties and shall reimburse to \*\*\* all costs, expenses liabilities and indemnifications arising from such actions. Neither Party may settle nor otherwise compromise any Patent Infringement Claim nor appeal without the other Party's written approval, such approval not to be unreasonably withheld or delayed.

12.2.3 Third Party Infringement. Each Party shall promptly report in writing to the other Party during the term of infringement of any of Palatin's Patents by use or exploitation by Third Party of the Product or any product competitive with the Product. \*\*\* has the primary right, at \*\*\* expense, to initiate a suit or take any other appropriate action, including compromising or settling any action that involves any Palatin Patent. If \*\*\* does not initiate a suit or take any other appropriate action within \*\*\* following receipt of notice of an infringement claim, then \*\*\* shall have the right, at \*\*\* expense, initiate a suit or take any other appropriate action in such country of Territory that it believes reasonably required to protect Palatin's Patents. In order to enable Gedeon Richter to take protective measures, upon Gedeon Richter's request, Palatin shall include Gedeon Richter in the patent-roll of the Palatin's Patent.

#### 13. INDEMNIFICATION

- 13.1 Palatin. Palatin shall indemnify, defend and hold harmless Gedeon Richter and its directors, officers, employees and agents (each a "Gedeon Richter Indemnitee") from and against any and all liabilities, damages, losses, costs or expenses (including reasonable attorneys' and professional fees and other expenses of litigation and/or arbitration) resulting from a claim, suit or proceeding made or brought by a Third Party against a Gedeon Richter Indemnitee arising from or occurring as a result of (a) the manufacture of any Investigational Product by or on behalf of Palatin, (b) any breach of the representations and warranties set forth in Sections 11.1 and 11.2, and (c) any gross negligence or willful misconduct on the part of Palatin, except to the extent any of the foregoing were caused by the gross negligence or willful misconduct of Gedeon Richter or breach of any term of this Agreement by Gedeon Richter.
- 13.2 Gedeon Richter. Gedeon Richter shall indemnify, defend and hold harmless Palatin and its directors, officers, employees and agents (each a "Palatin Indemnitee") from and against any and all liabilities, damages, losses, costs or expenses (including reasonable attorneys' and professional fees and other expenses of litigation and/or arbitration) resulting from a claim, suit or proceeding made or brought by a Third Party against a Palatin Indemnitee, arising from or occurring as a result of (a) any breach of the representations and warranties set forth in Section 11.1, or (b) any development, testing, importation, use, offer for sale, sale or other distribution of any Product by Gedeon Richter or its Affiliates and Sublicensees, except to the extent caused by the gross negligence or willful misconduct of Palatin or breach of any term of this Agreement by Palatin.
- 13.3 <u>Procedure.</u> In the event that any Indemnitee intends to claim indemnification under this Article 13 it shall notify the other Party (the "Indemnitor") in writing of such claim as soon as reasonably practicable after the Indemnitee receives notice of the claim. The Indemnitor shall have the sole right to control the defense of the claim (including the right to settle the claim solely for monetary consideration). The Indemnitee shall cooperate with the Indemnitor and its legal representatives in the investigation of any action, claim or liability covered by this Article 13 and do nothing which would adversely affect such defense or settlement. No settlement with respect to any such claim shall serve to establish liability on the part of any Indemnitee without the express written consent of such Indemnitee. The Indemnitee shall not, except at its own cost, voluntarily make any payment or incur any expense with respect to any claim or suit without the prior written consent of the Indemnitor, which the Indemnitor shall not be required to give.
- 13.4 <u>Limitation of Liability</u>. EXCEPT WITH RESPECT TO DAMAGES AWARDED TO A THIRD PARTY BY A COURT OF COMPETENT JURISDICTION THAT ARE REQUIRED TO BE INDEMNIFIED, AND EXCEPT IN THE CASE OF A BREACH OF THE CONFIDENTIALITY OBLIGATIONS SET FORTH IN ARTICLE 10 OF THIS AGREEMENT, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES OR LOSS OF PROFIT ARISING OUT OF OR RELATED TO THE PERFORMANCE OF THEIR RESPECTIVE RESPONSIBILITIES UNDER THIS AGREEMENT.
  - 13.5 <u>Survival</u>. This Article 13 will survive expiry or termination of this Agreement for any reason.

## 14. TERM AND TERMINATION

14.1 <u>Term</u>. The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Article 14, expire on \*\*\*. This Agreement shall expire in its entirety \*\*\*.

#### 14.2 Termination for Material Breach.

14.2.1 In the case that one of the Parties believes that the other Party has materially breached the Agreement, the Joint Steering Committee shall be notified and meet as soon as possible in order that the Parties attempt to resolve any dispute as to the existence of any such material breach. Failing a consensus decision by the Joint Steering Committee within \*\*\* of receiving the matter for review, it shall then be referred for resolution as set forth in Section 15.2.1. Failing a resolution within \*\*\* of receiving the matter for review from the Joint Steering Committee, the non-breaching Party may then proceed to give written notice of termination for material breach.

14.2.2 If pursuant to Section 14.2.1, either Party gives written notice to the other Party of termination for material breach, which notice shall describe such material breach in reasonable detail and whether it has been deemed non-curable or curable by the Joint Steering Committee and the Chief Executive Officers, this Agreement and the rights and options granted herein may be terminated by the non-breaching Party, effective \*\*\* after giving written notice to the breaching Party of termination for non-curable breach, \*\*\* after giving written notice to the breaching Party of such termination in the case of a curable payment breach, and \*\*\* after giving written notice to the breaching Party of such termination in the case of any other curable breach. The foregoing notwithstanding, if any curable material breach is cured within the aforesaid \*\*\* or \*\*\* period, the notice shall be automatically withdrawn and of no effect.

14.2.3 If Gedeon Richter has the right to terminate this Agreement pursuant to Section 14.2.2 for Palatin's material breach, Gedeon Richter may elect, by written notice to Palatin, not to terminate this Agreement and instead to retain this Agreement in effect (including, without limitation, with respect to \*\*\*), in which case Palatin shall continue to be liable to Gedeon Richter for any uncured material breach, and Gedeon Richter shall be entitled to pursue resolution pursuant to Section 15.2.2. Following a final resolution pursuant to Section 15.2.2 (unless Palatin in writing does not dispute Gedeon Richter's determination of Palatin's material breach) of Palatin's material breach of this Agreement, Gedeon Richter may elect, in lieu of receiving a payment of damages from Palatin, to offset Gedeon Richter's future payment obligations to Palatin under this Agreement by the amount of damages determined and awarded to Gedeon Richter pursuant to Section 15.2.2 (or agreed to in writing by the Parties). For purposes of the immediately preceding sentence, a final resolution with respect to a dispute relating to intellectual property or a breach of the confidentiality obligations of this Agreement means a final, non-appealable judgment by a court of competent jurisdiction.

- 14.2.4 Any exercise by the Parties of their rights under Section 14.2.2 may be on a country-by-country basis, in the non-breaching Party's discretion, in which case such termination shall be partial in nature and shall only apply to the particular country which is the source of the alleged material breach. Furthermore, Palatin shall have the alternative option, in its sole discretion, instead of terminating the Agreement in part or in whole, to convert the exclusive appointment of Gedeon Richter under Article 2 of this Agreement into a non-exclusive appointment, and to apply such non-exclusive status on a country-by-country basis, in the non-breaching Party's discretion, in which case such non-exclusivity shall only apply to the particular country which is the source of the alleged material breach.
- 14.3 <u>Termination for Insolvency</u>. If voluntary or involuntary proceedings by or against a Party are instituted in bankruptcy under any insolvency law, or a receiver or custodian is appointed for such Party, or proceedings are instituted by or against such Party for corporate reorganization or the dissolution of such Party, which proceedings, if involuntary, shall not have been dismissed within \*\*\* after the date of filling, or if such Party makes an assignment for the benefit of creditors, or substantially all of the assets of such Party are seized or attached and not released within \*\*\* thereafter, the other Party may terminate this Agreement effective immediately upon notice of such termination. Upon a termination of this Agreement pursuant to this Section 14.3 as a result of Palatin's insolvency, Gedeon Richter's License will be deemed fully paid-up and royalty-free, perpetual and irrevocable and Gedeon Richter shall have the right to retain the Regulatory Approvals.
- 14.4 <u>Termination for Regulatory Purposes</u>. Gedeon Richter may terminate this Agreement in its entirety or in part, and on a country-by-country basis: (a) if upon completion of all activities contemplated by the Gedeon Richter Development Plan the results of the Development activities prove to be unsatisfactory to proceed with the registration procedure in the Territory by no fault of Gedeon Richter, and such unsatisfactory results cannot be cured through Commercially Reasonable Efforts of Gedeon Richter, or (b) if the Competent Authorities do not grant Regulatory Approval in the Territory by no fault of Gedeon Richter, or (c) if the Competent Authorities withdraw the Regulatory Approval(s) in any countries of the Territory by no fault of Gedeon Richter or Gedeon Richter voluntary withdraws the Regulatory Approval(s) or the Marketing Authorization Application(s) in any country of the Territory due to serious safety concerns. In the event of a termination pursuant to this Section 14.4, Gedeon Richter shall not be obliged to pay to Palatin the remaining milestone payments.
- 14.5 Force Majeure Event. If a Party suffers a delay or default in performing any of its respective obligations hereunder because of a force majeure event caused by conditions beyond either Party's reasonable control which may, but do not necessarily include acts of God, government restrictions (including export and import restrictions), wars, insurrections, labor disturbances, shortages of equipment, fuel or labor, destruction of facilities or materials by fire, earthquake, storm or other casualty, judgment or injunction of any court, epidemic, or failure of public utilities or common carrier (the "Force Majeure Event"), it shall promptly notify the other Party in writing of the reasons for the delay or default and shall use and continue to use Commercially Reasonable Efforts to avoid, remove or mitigate such causes of non-performance. In case a Party does not perform its obligations hereunder for a period of \*\*\* as a result of a Force Majeure Event, the other Party shall have the right to terminate this Agreement in its entirety upon providing written notice to the non-performing Party, such termination to be effective \*\*\* after such notice if the Force Majeure Event has not theretofore terminated.

#### 14.6 Effects of Termination.

14.6.1 <u>Accrued Rights and Obligations</u>. Termination of this Agreement for any reason shall not release any Party hereto from any liability which, at the time of such termination, has already accrued to the other Party or which is attributable to a period prior to such termination nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement. It is understood and agreed that monetary damages may not be a sufficient remedy for any breach of this Agreement and that the non-breaching Party may be entitled to injunctive relief as a remedy for any such breach.

14.6.2 <u>Survival</u>. The rights and obligations set forth in this Agreement shall extend beyond the term or termination of this Agreement only to the extent expressly provided for herein, or to the extent that the survival of such rights or obligations are necessary to permit their complete fulfillment or discharge.

14.6.3 <u>License</u>. Upon expiration of this Agreement or termination pursuant to Section 14.2 as a result of Palatin's material breach or pursuant to Section 14.3 as a result of Palatin's insolvency, Gedeon Richter's License will be deemed fully paid-up and royalty-free, perpetual and irrevocable.

14.6.4 <u>Transfer of Know-How to Palatin</u>. Upon a termination of this Agreement pursuant to Section 14.2 as a result of Gedeon Richter's material breach, pursuant to Section 14.3 as a result of Gedeon Richter's insolvency, pursuant to Section 14.4 or pursuant to Section 14.5 as a result of a Force Majeure Event preventing performance by Gedeon Richter, (a) Gedeon Richter shall promptly return to Palatin all Palatin Know-How in tangible form and (b) Gedeon Richter shall promptly transfer and assign to Palatin, for no additional consideration, all Gedeon Richter Know-How in tangible form. Notwithstanding the foregoing, Gedeon Richter's counsel may retain one (1) copy of such tangible Palatin Know-How and Gedeon Richter Know-How for archival purposes and for ensuring compliance with Article 10.

14.6.5 <u>Transfer of Know-How to Gedeon Richter</u>. Upon a termination of this Agreement pursuant to Section 14.2 as a result of Palatin's material breach, pursuant to Section 14.3 as a result of Palatin's insolvency or pursuant to Section 14.5 as a result of a Force Majeure Event preventing performance by Palatin, (a) Palatin shall promptly return to Gedeon Richter all Gedeon Richter Know-How in tangible form and (b) Gedeon Richter thereafter automatically shall have, as of the effective date of the termination, a royalty-free license (including the right to sublicense) under the Palatin Know-How to the extent necessary for the Development and Commercialization of the Product in the Field in the Territory. Notwithstanding the foregoing, Palatin's counsel may retain one (1) copy of such tangible Gedeon Richter Know-How for archival purposes and for ensuring compliance with Article 10.

14.6.6 Regulatory Approvals. Upon Palatin's written request submitted to Gedeon Richter within \*\*\* following a termination of the Agreement pursuant to Section 14.2 as a result of Gedeon Richter's material breach, pursuant to Section 14.3 as a result of Gedeon Richter's insolvency, pursuant to Section 14.4 or pursuant to Section 14.5 as a result of a Force Majeure Event preventing performance by Gedeon Richter, Gedeon Richter will initiate the transfer or assignment of the Regulatory Approvals to Palatin or to a Third Party designated by Palatin. Upon expiration of this Agreement or termination pursuant to Section 14.2 as a result of Palatin's material breach, pursuant to Section 14.3 as a result of Palatin's insolvency or pursuant to Section 14.5 as a result of a Force Majeure Event preventing performance by Palatin, Gedeon Richter shall have the right to retain the Regulatory Approvals. Except in the case of a termination pursuant to Section 14.2 as a result of Gedeon Richter's material breach, Palatin shall reimburse Gedeon Richter for all out-of-pocket costs actually incurred by Gedeon Richter in connection with the transfer or assignment of the Regulatory Approvals pursuant to this Section 14.6.6. Gedeon Richter shall provide all necessary assistance to Palatin for such transfer at Gedeon Richter's cost. Gedeon Richter shall be entitled to withdraw the Regulatory Approvals if Palatin does not request the transfer or assignment of the Regulatory Approvals in writing within \*\*\* following such termination.

14.6.7 Stock on Hand. Upon a termination of the Agreement pursuant to Section 14.3 as a result of Gedeon Richter's insolvency, pursuant to Section 14.4 or pursuant to Section 14.5, Gedeon Richter shall have the right to sell or otherwise dispose of the stock of any Product subject to this Agreement then on hand until the date that is \*\*\* after the effective date of such termination. Sales made pursuant to this Section 14.6.7 shall be treated as Net Sales and royalty thereon shall be paid to Palatin.

## 15. GOVERNING LAW, DISPUTES AND ARBITRATION

- 15.1 Governing Law. This Agreement shall be governed in all respects by the laws of \*\*\*, excluding its conflicts of laws principles.
- 15.2 Disputes and Arbitration.

15.2.1 In the event of a dispute arising between the Parties concerning the interpretation or performance of this Agreement, upon either Party's written request, the matter will be submitted to the Chief Executive Officers of the Parties for good faith negotiation and resolution. In the event the Chief Executive Officers are also unable to resolve such dispute within \*\*\* after such request is received, either Party may invoke the provisions Section 15.2.2.

15.2.2 Except with respect to disputes relating to intellectual property or a breach of the confidentiality obligations of this Agreement, any dispute, controversy or claim arising out of or in relation to this Agreement, including the validity, invalidity, breach or termination thereof which cannot be settled amicably by the Parties in accordance with Section 15.2.1 shall be resolved by arbitration in accordance with the Rules of Arbitration of the International Chamber of Commerce in force on the date when the notice of arbitration is submitted in accordance with such rules. Any arbitration shall be held in \*\*\* and conducted in English by a panel of three arbitrators. The award shall be final and binding upon the Parties and shall be the sole and exclusive remedy between the Parties regarding the claims, counterclaims, issues, or accounting presented to the arbitrators. Notwithstanding the foregoing, each Party may at any time pursue equitable remedies, including without limitation injunctive relief, to protect its Confidential Information and its intellectual property rights. With respect to disputes relating to intellectual property or a breach of the confidentiality obligations of this Agreement, each Party shall have the right to pursue any legal or equitable remedy available to it under applicable laws.

## 16. INSURANCE

16.1 During the term of this Agreement and for a period of \*\*\* following the termination or expiration of this Agreement, each Party shall maintain in full force and effect a policy of insurance or self-insurance against liability and other risks associated with its activities and obligations under this Agreement, including its Clinical Studies, in such amounts and on such terms as are consistent with the normal business practices of prudent companies similarly situated.

#### 17. MISCELLANEOUS

- 17.1 <u>Independent Contractors</u>. The relationship of the Parties hereto is that of independent contractors, and nothing in this Agreement shall be construed to give either Party the power or authority to act for, bind or commit the other Party in any way. Nothing herein shall be construed to create the relationship of agents, partners or joint venture partners between the Parties for any purpose.
- 17.2 Assignment. This Agreement may not be assigned or otherwise transferred by either Party to any Third Party without the prior written consent of the other Party, such consent not to be unreasonably withheld; provided, however, that either Party may assign this Agreement, without such consent, to its Affiliate or to a Third Party in connection with a Change of Control. Any successor or permitted assignee of rights and/or obligations hereunder shall, prior to such assignment or Change of Control, agree in writing to assume the existing and future obligations, rights, title and interest in, to and under this Agreement of the Party with which it is entering into such Change of Control transaction. If any successor or permitted assignee of rights and/or obligations hereunder does not provide such written assumption prior to such assignment or Change of Control, this Agreement shall be deemed to have been materially breached by the Target Party immediately prior to the consummation of the Change of Control. This Agreement shall be binding upon and inure to the benefit of the Parties and their successors and permitted assigns. Any assignment or attempted assignment by either Party in violation of the terms of this Section 17.2 shall be null, void and of no legal effect.
- 17.3 <u>Notices</u>. All notices, requests and other communications hereunder shall be in writing and shall be personally delivered or sent by telecopy or other electronic facsimile transmission, by registered or certified mail, return receipt requested, postage prepaid, or by overnight courier, in each case to the Parties' respective addresses specified below, or such other address as may be specified by written notice delivered to the other Party in accordance with this Section 17.3:

If to Palatin:
Palatin Technologies, Inc.
4-B Cedar Brook Drive
Cranbury, New Jersey 08512
USA

If to Gedeon Richter:

Chemical Works of Gedeon Richter Plc. Budapest 1103 Gyömrői út 19-21. Hungary

- 17.4 <u>Advice of Counsel</u>. Palatin and Gedeon Richter have each consulted counsel of their choice regarding this Agreement, and each acknowledges and agrees that this Agreement shall not be deemed to have been drafted by one Party or another and will be construed accordingly.
- 17.5 <u>Governing Language</u>. This Agreement has been executed in English. If any translation of this Agreement conflicts with the English version or contains terms in addition to or different from the English version, the English version shall prevail.
- 17.6 <u>Further Assurances</u>. Each Party agrees to execute, acknowledge and deliver such further consents, documents and instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 17.7 Severability. In the event that any provisions of this Agreement are determined to be invalid or unenforceable by a court of competent jurisdiction, the remainder of the Agreement shall remain in full force and effect without said provision. In such event the Parties shall, in good faith, negotiate a substitute clause for any provision declared invalid or unenforceable, which shall most nearly approximate the intent of the Parties entering this Agreement.
- 17.8 <u>Waiver</u>. It is agreed that no waiver by either Party hereto of any breach of default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default.
- 17.9 <u>Complete Agreement</u>. This Agreement, the Supply Agreement for Development and the Commercial Supply Agreement and that certain Confidential Information Disclosure Agreement entered into by and between the Parties as of \*\*\*, constitute the entire agreement, both written and oral, between the Parties with respect to the subject matter hereof, and that all prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, are merged and canceled, and are null and void and of no effect. No amendment or change hereof or addition hereto shall be effective or binding on either of the Parties hereto unless reduced to writing and duly executed on behalf of both Parties.

The Exhibits form an integral part of this Agreement and references to this Agreement include the Exhibits as well.

- 17.10 <u>Use of Name</u>. Neither Party shall use the name or trademarks of the other Party without the prior written consent of such other Party except in connection with the disclosure of the existence of this Agreement.
- 17.11 <u>Headings</u>. The captions to the several Articles and Sections hereof are not a part of this Agreement, but are included merely for convenience of reference only and shall not affect its meaning or interpretation.
- 17.12 <u>Counterparts</u>. This Agreement may be executed in two counterparts, each of which shall be deemed an original and which together shall constitute one instrument.

IN WITNESS WHEREOF Palatin and Gedeon Richter have executed this Agreement by their respective duly authorized representatives.

2014

PALATIN TECHNOLOGIES, INC.

CHEMICAL WORKS OF GEDEON

RICHTER PLC.

Date: 29 August 2014

Date:

August

Budapest,

29,

By: <u>/s/ Carl Spana</u>
Print Name: Carl Spana

Title: President and Chief Executive Officer

By: /s/ Erik Bogsch

Print Name: Erik Bogsch Title: Managing director

Date: 29 August 2014

By: <u>/s/ Stephen T. Wills</u>
Print Name: Stephen T. Wills

Title: Chief Financial Officer and Chief Operating Officer

EXHIBIT I

**Territory** 

**EXHIBIT II** 

# Palatin Know-How

#### **EXHIBIT III**

#### **Palatin Patent**

The Palatin Patent consists of the following patent applications and patents, including (a) all reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; and (b) all extensions, renewals or restorations of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof:

**Issued Patents** 

**					
<b>Country Name</b>	Application Number	Date Filed	Patent Number	Grant Date	Status
			***		
Pending Application	<u>ıs</u>				
**					
			23		

# **EXHIBIT IV**

# Countries Subject to Right of First Offer and Negotiation

Exhibit V

# Palatin Development Plan

Exhibit VI

# **Gedeon Richter Development Plan**

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Exhibit VII

# **Third Party Manufacturers**

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Exhibit 21

### SUBSIDIARIES OF THE REGISTRANT

			Name Under Which	
Name of Subsidiary		State of Incorporation	Subsidiary Does Business	
Rho	Med Incorporated	New Mexico	RhoMed Incorporated	

#### **Consent of Independent Registered Public Accounting Firm**

The Board of Directors
Palatin Technologies, Inc.:

We consent to the incorporation by reference in the registration statements (Nos. 333-33569, 333-5605, 333-64951, 333-72873, 333-84421, 333-52024, 333-54918, 333-74990, 333-100469, 333-101764, 333-104370, 333-112908, 333-128585, 333-132369, 333-140648, 333-146392, 333-170227, 333-174251, 333-183837, and 333-185113) on Form S-3 and the registration statements (Nos. 333-57079, 333-83876, 333-128854, 333-149093, 333-163158, 333-174257, and 333-191467) on Form S-8 of Palatin Technologies, Inc. of our report dated September 12, 2014, with respect to the consolidated balance sheets of Palatin Technologies, Inc. and subsidiary as of June 30, 2014 and 2013, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended June 30, 2014, which report appears in the June 30, 2014 annual report on Form 10-K of Palatin Technologies, Inc.

Philadelphia, Pennsylvania September 12, 2014

#### Certification of Chief Executive Officer

#### I, Carl Spana, certify that:

- 1. I have reviewed this Annual Report on Form 10-K of Palatin Technologies, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 12, 2014

/s/ Carl Spana

Carl Spana, President and Chief Executive Officer

#### Certification of Chief Financial Officer

- I, Stephen T. Wills, certify that:
  - 1. I have reviewed this Annual Report on Form 10-K of Palatin Technologies, Inc.;
  - 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
  - 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
  - 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
    - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
    - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
  - 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:
    - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 12, 2014

/s/ Stephen T. Wills

Stephen T. Wills, Executive Vice President, Chief Financial Officer and Chief Operating Officer

# Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350 As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Carl Spana, President and Chief Executive Officer of Palatin Technologies, Inc., hereby certify, to my knowledge, that the Annual Report on Form 10-K for the year ended June 30, 2014 of Palatin Technologies, Inc. (the "Form 10-K") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Palatin Technologies, Inc.

Dated: September 12, 2014

/s/ Carl Spana

Carl Spana, President and Chief Executive Officer (Principal Executive Officer)

# Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350 As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Stephen T. Wills, Executive Vice President, Chief Financial Officer and Chief Operating Officer of Palatin Technologies, Inc., hereby certify, to my knowledge, that the Annual Report on Form 10-K for the year ended June 30, 2014 of Palatin Technologies, Inc. (the "Form 10-K") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Palatin Technologies, Inc.

Dated: September 12, 2014

/s/ Stephen T. Wills

Stephen T. Wills, Executive Vice President, Chief Financial Officer and Chief Operating Officer (Principal Financial Officer)