PALATIN TECHNOLOGIES INC
Form 10-K
September 29, 2008

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

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended June 30, 2008

or

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

For the transition period from _____ to _____

Commission file number 001-15543

_____

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

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

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

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $.01 per share	American Stock Exchange

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

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

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates, computed by reference to the price at which the common stock 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, 2007): $17,018,365.

Indicate the number of shares outstanding of each of the registrant s classes of common stock, as of the latest practicable date (September 26, 2008): 85,524,077

PALATIN TECHNOLOGIES, INC.
TABLE OF CONTENTS

Table of Contents

PART I

Item 1. Business.

Forward-looking statements

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

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

Overview

We are a biopharmaceutical company dedicated to the development of peptide, peptide mimetic and small molecule compounds with a focus on melanocortin and natriuretic peptide receptor systems. We have a diverse pipeline of active development programs, including development of proposed products in the cardiovascular field for treatment of heart failure, hard-to-control hypertension and for cardiac surgery organ protection, and proposed products for sexual dysfunction, obesity and metabolic syndrome. 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, ischemia reperfusion injury (injury resulting from inadequate blood flow or reintroduction of blood flow), hemorrhagic shock 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 heart failure, hypertension and other cardiovascular diseases.

We have the following products in development:

PL-3994, a peptidomimetic natriuretic peptide receptor A (NPRA) agonist, for treatment of heart failure (HF), including chronic HF and acute HF.

PL-3994 for treatment of difficult-to-control hypertension, including dialysis patients with hypertension.

Bremelanotide, a peptide melanocortin receptor agonist, for prevention of organ damage secondary to cardiac surgery and related indications.

PL-6983, a peptide melanocortin receptor agonist, for treatment of female sexual dysfunction.

Melanocortin receptor-based compounds for treatment of obesity and related metabolic syndrome pursuant to an ongoing research collaboration and global license with AstraZeneca AB.

NeutroSpec®, a radiolabeled monoclonal antibody product for imaging and diagnosing infection, which is the subject of a strategic collaboration agreement with the Mallinckrodt division of Covidien Ltd. (Mallinckrodt). We have suspended ongoing clinical trials and regulatory approvals of NeutroSpec while we and Mallinckrodt evaluate future development and marketing activities involving NeutroSpec.

Key elements of our business strategy include: entering into alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of product candidates we are developing; partially funding our development and discovery programs with the cash flow from our collaboration agreements; and, depending on the availability of sufficient funding, expanding our pipeline by using our expertise in drug discovery technologies for melanocortin and natriuretic peptide receptor systems and acquiring synergistic products and technologies.

We incorporated in Delaware in 1986 and commenced operations in the biopharmaceutical area in 1996. Our corporate offices and research and development facility are located at 4C Cedar Brook Drive, Cranbury, New

Table of Contents

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 shall not be deemed to be incorporated into this Annual Report.

Products and Technologies in Research and Development

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

PL-3994 is one of a number of natriuretic peptide receptor agonist compounds we have developed, which are the subject of pending patent applications in the United States and selected foreign countries. PL-3994 is a synthetic molecule incorporating a novel and proprietary amino acid mimetic structure. It has an extended half-life, with reduced affinity for endogenous natriuretic peptide clearance receptors and significantly increased resistance to neutral endopeptidase, an endogenous enzyme that degrades natriuretic peptides.

Preclinical studies in animals established a dose-dependent effect on blood pressure and diuresis, and in animal models of HF showed improved kidney function and prevention of cardiac hypertrophy (increase in heart size due to disease). Safety toxicology studies were conducted in animals prior to filing an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA).

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

In the second quarter of calendar year 2008, we conducted a Phase 2a trial in volunteers with controlled hypertension who were receiving one or more conventional antihypertensive medications. In this trial, which was a randomized, double-blind, placebo-controlled, single ascending dose study in 21 volunteers, the objective was to demonstrate that PL-3994 can be given safely to patients taking antihypertensive medications commonly used in HF 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.

One further Phase 2 trial is planned in patients with worsening HF, which will evaluate whether a single subcutaneous dose of PL-3994, administered to patients who require hospitalization due to worsening HF, can achieve a clinically meaningful benefit on pulmonary capillary wedge pressure, a cardiac function test, and symptoms with an acceptable safety profile. This trial is projected to commence, depending on sufficient funding, during the fourth quarter of calendar year 2008 or first quarter of calendar year 2009. A second Phase 2 trial is planned in patients with chronic HF, and will evaluate safety profiles in patients given repeat doses of PL-3994 as well as pharmacokinetic and pharmacodynamic endpoints. This trial is projected to commence, depending on sufficient funding, during the first half of calendar year 2009.

PL-3994 activates NPRA, a receptor known to play a role in cardiovascular homeostasis. We believe that PL-3994, through activation of NPRA, will reduce cardiac hypertrophy, which is an independent risk factor for cardiovascular morbidity and mortality. PL-3994 increases plasma cGMP levels, a pharmacological response consistent with the effects of endogenous natriuretic peptides on cardiovascular function. 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 HF patients, leading to worsening of cardiovascular function.

PL-3994 is being developed as a subcutaneously administered drug, and is well absorbed through this route of administration. In human studies, the pharmacokinetic (period to metabolize or excrete the drug) and pharmacodynamic (period of action or effect of the drug) half-lives were on the order of hours, significantly longer

Table of Contents

than the comparable half-lives of endogenous natriuretic peptides. We believe that PL-3994, if successful, may be amenable to self-administration by patients, similar to insulin and other self-administered drugs.

Over five million Americans suffer from HF, with 550,000 new cases of HF diagnosed each year, with disease incidence expected to increase with the aging of the American population. Despite the treatment of HF with multiple drugs, almost all HF patients will experience at least one episode of acute HF that requires treatment with intravenous medications in the hospital. Heart failure has tremendous human and financial costs. Estimated direct costs in the U.S. for HF were $29.6 billion in 2006, with HF constituting the leading cause of hospitalization in people over 65 years of age, with over 1,100,000 hospitalizations for HF in 2004. Heart failure is also a high mortality disease, with approximately one-half of HF patients dying within five years of initial diagnosis.

PL-3994 for Difficult-to-Control Hypertension Indications. PL-3994 is also being developed for treatment of hypertension associated with kidney dialysis, resistant hypertension and other difficult-to-control hypertension indications. Resistant hypertension, which is high blood pressure despite a three-drug regimen that includes a diuretic, is commonly found in patients with congestive HF or renal disease. Adequate hypertension control is difficult with some patient populations, including patients on renal dialysis who may experience hypertension between dialysis sessions. While there are a large number of approved drugs for treatment of hypertension, there are no approved drugs for hypertension that are active through the NPRA system. Resistant and other difficult-to-control hypertension can be caused by increased aldosterone levels. PL-3994 is believed to decrease activity of the RAAS through the NPRA system, decreasing renin and aldosterone secretion and thereby decreasing blood pressure.

Preclinical and clinical trials to date with PL-3994 are described under the heading PL-3994 for Heart Failure Indications. A Phase 2 dose ranging and safety trial with PL-3994 is being considered with renal dialysis patients who have interdialytic hypertension (episodes of hypertension between dialysis sessions). Commencement of this trial is dependent on results from PL-3994 HF trials and sufficient funding to support the trial.

Over 300,000 Americans are on dialysis. Hypertension, particularly interdialytic hypertension, is a common finding in dialysis patients. Based upon multiple studies, 50 to 60 percent of hemodialysis patients and nearly 30 percent of peritoneal dialysis patients are hypertensive.

Another potential indication for PL-3994 is post-operative hypertension. Post-operative patients are limited in their ability to take oral medications, and thus a subcutaneously injected antihypertensive medication may provide a useful treatment tool.

With the mechanism of action of PL-3994, it may be possible to control hypertension in patient populations not adequately controlled by currently available drugs. These populations are among the most difficult to treat and control dialysis patients with interdialytic hypertension, post-operative patients and patients with resistant hypertension.

Bremelanotide for Organ Protection and Related Indications. Organ damage, particularly kidney damage, is a recognized complication of many surgical procedures, including cardiac surgeries involving cardiopulmonary bypass (the use of a heart-lung machine to support blood circulation and oxygenation during surgery on the heart). Cardiopulmonary bypass is used with most coronary artery bypass graft surgeries. Patients with acute renal (kidney) failure resulting from surgery have higher death rates, longer hospital stays, and may require dialysis. Ischemia reperfusion injury and inflammation are believed to be primary contributors to surgically-induced organ injury. The kidneys, which have high metabolic requirements, are particularly vulnerable to this type of injury. The brain, liver, lungs and gut may also suffer injury following cardiopulmonary bypass or high blood-loss surgeries.

Bremelanotide has been studied extensively by us for sexual dysfunction in nasal formulations and in subcutaneously and intravenously injected formulations. In these trials, almost 2,000 patients received at least one dose of bremelanotide, with about 1,500 receiving multiple doses. Increases in blood pressure were observed in some patients, and this observed increase was a significant factor leading us to discontinue work on bremelanotide as a first-line therapy for sexual dysfunction.

There are no approved drugs for prevention of acute renal injury secondary to cardiac surgery. This remains a major unmet medical need. We are developing bremelanotide for this and related indications. We have demonstrated increased survival rates and organ protection following administration of bremelanotide in a hemorrhagic shock rat model. Substantially less damage to the liver, kidneys and gut was seen in animals administered bremelanotide compared to control animals. Dose-responsive increases in blood pressure were also seen, together with improved maintenance of core body temperature and cardiac function. Bremelanotide also prevented metabolic acidosis (decrease in blood pH) following induced shock. We are continuing to conduct dose

Table of Contents

ranging and other preclinical studies in animal models preparatory to initiating human clinical trials for this indication.

Following completion of ongoing animal dose-ranging studies and preclinical studies, we are considering initiating a Phase 2 study on patients undergoing cardiopulmonary bypass surgery. This study would examine a number of endpoints, including measurement of kidney function post-surgery. Commencement of the Phase 2 study is dependent on sufficient funding to support the trial and FDA approval.

Acute renal failure remains a major complication of cardiopulmonary bypass surgery that is strongly associated with in-hospital mortality. Over 450,000 coronary artery bypass graft surgeries are performed annually in the United States. The incidence rate of acute renal failure has increased in recent years, resulting in increases in healthcare resource utilization and length of intensive care and hospital stay. Other potential indications for bremelanotide include improvement in survival and prevention of organ dysfunction in patients with traumatic injuries resulting in hemorrhagic shock. This patient population includes potential emergency medicine and military applications.

PL-6983 for Treatment of Female Sexual Dysfunction. PL-6983 is our lead compound in a new series of melanocortin receptor-specific peptides we have developed. We have demonstrated efficacy of PL-6983 in inducing erections in animal models and in inducing sexual behavior in an animal model of female sexual dysfunction (FSD). FSD is a multifactorial condition that has anatomical, physiological, medical, psychological and social components. Studies estimate FSD is prevalent in approximately 50% of women over the age of 30 and that more than 35 million women in the United States may be afflicted with some form of FSD. FSD includes disorders associated with desire, arousal, orgasm and pain.

In developing PL-6983, we used a novel screening platform that examined the effectiveness of peptides in animal models of sexual response and also determined cardiovascular effects, primarily looking at changes in blood pressure. In these animal models, PL-6983 resulted in significantly smaller increases in blood pressure at doses effective for a sexual response than blood pressure increases in the same models seen with bremelanotide. We discontinued development of bremelanotide for sexual dysfunction after the FDA raised concerns about the acceptable benefit/risk ratio of bremelanotide as a first-line therapy for erectile dysfunction, primarily because of increases in blood pressure observed in some patients.

We are developing PL-6983 primarily for FSD, a major unmet medical need. We are planning preclinical toxicology and other studies required by the FDA prior to initiating human clinical trials. Initial human clinical trials will be designed to measure safety parameters, including changes in blood pressure following administration. We anticipate that these initial studies will be conducted in men and women, but assuming favorable efficacy results without significant increases in blood pressure, future studies would be conducted in women with FSD. Depending on results of clinical trials, we may also seek to develop PL-6983 for erectile dysfunction (ED).

Obesity. We have a development program for melanocortin receptor-targeted compounds for the treatment of obesity, diabetes and related metabolic syndrome. Obesity is a multifactorial condition with significant 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 some melanocortin receptor agonists decrease food intake and induce weight loss.

Obesity is a significant healthcare issue, often correlated with a variety of cardiovascular and other diseases, including diabetes. More than 1.1 billion adults and over 150 million children worldwide are overweight, with over 300 million adults categorized as obese. According to the American Obesity Association, obesity is the second leading cause of preventable death after smoking and nearly one-third of adults in the United States are obese. Increased mortality, high blood pressure, diabetes and other substantial health risks are associated with being overweight and obese. Over 2.6 million deaths are attributed to diabetes each year worldwide and almost $120 billion is spent on related costs of obesity, according to the U.S. Surgeon General.

We have developed classes of small molecule and peptide compounds targeting melanocortin receptors which are effective in the treatment of obesity in animal models but which induce a limited or no sexual response. Certain of these compounds have been demonstrated to be effective in normal diet-induced obese and genetically obese animal models for decreasing food intake and body weight, without an increase in sexual response in normal animals at the same or higher dose levels. Tests to date have been conducted only in animal models and in laboratory tests.

In 2007, we entered into an exclusive global licensing and research collaboration agreement with AstraZeneca to discover, develop and commercialize compounds that target melanocortin receptors for the treatment

Table of Contents

of obesity, diabetes and related metabolic syndrome. In June 2008, the collaboration agreement was amended to include additional compounds and associated intellectual property we developed. Pursuant to the terms of the agreement, we received an up-front payment of $10 million from AstraZeneca and are eligible for milestone payments totaling up to $300 million, with up to $180 million contingent upon development and regulatory milestones and the balance on achievement of sales targets, plus royalties on sales of approved products. We anticipate receiving a significant milestone payment from AstraZeneca by the end of the first quarter of calendar year 2009, provided we achieve specified objectives by that time. AstraZeneca has assumed responsibility for product commercialization, product discovery and development costs. We are providing certain scientific expertise in the research collaboration at a negotiated rate.

NeutroSpec. We are evaluating future development and marketing activities involving NeutroSpec, our trade name for technetium (99m Tc) fanolesomab, a radiolabeled monoclonal antibody product for imaging and diagnosing infection, with Mallinckrodt, with whom we entered into a strategic collaboration agreement in 1999. NeutroSpec includes an anti-CD 15 monoclonal antibody which selectively binds to neutrophils (a type of white blood cell involved in immune responses). When labeled with technetium (a radioactive tracer) and injected into the blood stream, the antibody binds to neutrophils accumulated at an infection site, labeling these cells. As a result, physicians can rapidly image and locate an infection using a gamma camera, a common piece of hospital equipment that detects radioactivity.

In July 2004, we received approval from the FDA to market NeutroSpec for imaging of patients with equivocal signs and symptoms of appendicitis who are five years of age or older. During 2005, we and Mallinckrodt reported to the FDA the occurrence of several serious adverse events, including two deaths, involving patients with severe underlying cardiopulmonary compromise who received NeutroSpec for off-label uses. In December 2005, the FDA informed Mallinckrodt and us that it had reconsidered the risk/benefit assessment of NeutroSpec and determined that the product should not be administered to patients, until a further understanding and review of the relationship between NeutroSpec and the reported serious adverse events is complete. We have reviewed data and conducted studies on the relationship between NeutroSpec use and the observed serious adverse events, but we and Mallinckrodt have not made a final decision concerning future activities involving NeutroSpec. We anticipate making a decision on whether to seek to proceed with NeutroSpec in the second half of calendar year 2008.

Our 1999 collaboration agreement with Mallinckrodt provides for marketing and distribution rights to NeutroSpec. Under this agreement, we are responsible for the manufacture of NeutroSpec and Mallinckrodt agreed to pay us a transfer price on each product unit sold to Mallinckrodt and a royalty on their net sales of NeutroSpec. If NeutroSpec is reintroduced to the market, we may receive milestone payments from Mallinckrodt on the achievement of development, regulatory or sales objectives; however, we may not be able to reintroduce NeutroSpec to the market or meet development or sales objectives.

Technologies We Use. We use 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 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 and difficult-to-control hypertension.

We maintain expertise in both peptide and small molecule chemistries, and have developed a series of drug selection technologies for selecting compounds with desired pharmacological profiles, particularly in the melanocortin receptor field. The drug selection technologies are used to develop and select melanocortin receptor-specific small molecules and peptides with novel properties, including compounds that are effective in the treatment of obesity in animal models but which induce a limited or no sexual response.

Some compound series have been derived using our proprietary and patented platform technology, called MIDAS (Metal Ion-induced Distinctive Array of Structures). This technology employs metal ions to fix the three-dimensional configuration of peptides, forming conformationally rigid molecules that remain folded specifically in their active state. These MIDAS molecules are 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 can be used to design small molecule, non-peptide drugs.

Table of Contents

Competition

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 industry is characterized by extensive research efforts and rapid technological change with many companies that have developed or are working to develop products similar to ours. 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 our future product candidates obsolete or non-competitive or that our collaborators or customers will not choose to use competing technologies or products.

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 HF patients who have dyspnea at rest or with minimal activity. Carperitide, a recombinant human atrial natriuretic peptide drug, is marketed in Japan and is reported to be available for licensing in other countries. Both nesiritide and carperitide are administered by intravenous infusion. Because of the very short half-life of nesiritide, we believe it is unlikely to be suitable for subcutaneous administration or for treatment of chronic HF. While PL-3994 may compete with nesiritide or carperitide for treatment of acute HF in a hospital setting, there is no NPRA agonist drug approved in the United States for treatment of chronic HF, including worsening HF. We are aware of at least one company developing natriuretic peptide drugs, with one drug reported to be in Phase 2 clinical trials for acute HF. In addition, there are a number of approved drugs and drugs in development for treatment of HF through mechanisms or pathways other than agonism of NPRA.

PL-3994 for Difficult-to-Control Hypertension Indications. While other natriuretic peptide drugs are marketed or under development, we are not aware of any NPRA agonist drug in development for difficult-to-control hypertension or related indications. However, there are a number of approved oral drugs for hypertension which work by a variety of mechanisms, including renal competitive aldosterone antagonists such as spirolactone. There are also several approved intravenous antihypertensive drugs which could compete with PL-3994 for certain indications, including post-operative hypertension. A number of approved drugs and drugs in development regulate effects of the RAAS, including inhibitors of angiotensin-converting enzyme (ACE inhibitors), angiotensin receptor blockers (ARBs), and renin receptor inhibitors. The antihypertensive drug market is highly competitive, with numerous drugs in various stages of development in addition to the marketed drugs.

Bremelanotide for Organ Protection and Related Indications. We are aware of one drug in clinical trials being developed to prevent post-surgical kidney injury after thoracic aortic aneurysm repair which is reported to act through the melanocortin receptor system. There are a number of other drugs and technologies in clinical studies for prevention or treatment of renal injury secondary to cardiac surgery. However, we are not aware of any drug approved in the United States for prevention of renal injury secondary to cardiac surgery.

PL-6983 for Treatment of Female Sexual Dysfunction. There is tremendous competition and incentive to develop, market and sell drugs for the treatment of FSD. A number of hormonal therapies have been commercialized, including progestin, androgen and localized estrogen therapies, but they have not gained widespread market acceptance. None are specifically approved for an FSD indication, and they are reported to be effective in a comparatively small percentage of FSD cases. Drugs approved for ED indications have been studied for use in treatment of FSD, primarily 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®). None are specifically approved for an FSD indication, and PDE-5 inhibitors are reported to be either ineffective or effective in limited FSD indications. Despite the fact that a number of drugs are in various stages of research or development for FSD, to our knowledge none utilize melanocortin pathways as the mechanism of action.

*Obesity.*There are several FDA-approved drugs 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, and we may not be able to proceed if

7

Table of Contents

AstraZeneca discontinues work under or terminates our January 2007 license agreement. 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.

NeutroSpec. Other imaging modalities, including computerized tomography (CT) and ultrasound technologies, are used for diagnosis of indications with which NeutroSpec may compete. There are FDA-approved products for attaching radiotracers to blood cells for use in imaging and locating infections. There is also at least one other company developing a technetium-labeled product for imaging infections, which is reported to be in Phase 2 clinical trials, as well as an antibody-based product marketed in some European countries which may compete with NeutroSpec for certain 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 43 issued United States patents and have over 25 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 issued United States and foreign patents claiming the bremelanotide substance, and have a pending United States provisional patent application claiming use of bremelanotide for prevention of organ damage and related uses. 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, referred to as 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 have patent applications pending in the United States and foreign countries claiming the PL-3994 substance and other natriuretic peptide receptor agonist compounds we have developed. However, these patent applications have not yet been examined, and we do not know the scope of patent claims that will be allowed, or whether any patents will issue.

We have a provisional patent application pending on melanocortin receptor-specific peptides including PL-6983, but have not yet filed either a United States utility patent application or patent applications in any foreign countries. Until these applications are filed and the patent applications examined, we do not know the scope of patent claims that will be allowed, or whether any patents will issue.

We have a number of United States and foreign patent applications claiming compounds included in our agreement with AstraZeneca relating to our obesity program. However, the majority of these patent applications have not yet been examined, and we do not know the scope of patent claims that will be allowed, or whether any patents will issue. Additionally, until one or more compounds are selected for commercialization, which may never occur, we cannot evaluate the duration of patents or their effect on the program.

We own patents relating to certain aspects of NeutroSpec, but the claims of those patents would not be effective in preventing others from developing competing products. In addition, the validity of these patents has not been determined. We have exclusive rights to the cell line which produces the monoclonal antibody used in NeutroSpec, but this protection requires maintaining the cell line as proprietary.

We own or have rights to United States and foreign patents and pending applications directed to radiolabeling of antibodies, antibody fragments, and peptides; MIDAS peptides; small molecules; and methods for making and using the foregoing in diagnostic and therapeutic applications.

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.

Table of Contents

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 U.S. patents which are infringed by PL-3994, bremelanotide, PL-6983 or NeutroSpec or by our methods of making the foregoing, 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 foreign 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 and marketing 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 clinical trial can be placed on clinical hold, or temporarily or permanently stopped 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 U.S. 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 either a biologics license application (BLA) or new drug application (NDA) from the FDA for any of our proposed products, any facility that manufactures such a product must comply with current good manufacturing practices (cGMPs). 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 cGMPs 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 cGMPs and other regulatory requirements.

Table of Contents

Third-Party Reimbursements

Successful sales of our proposed products in the United States and other countries will depend on the availability of adequate reimbursement from third-party payors such as governmental entities, managed care organizations and private insurance plans. Reimbursement by a third-party payor may depend on a number of factors, including the payor s determination that the product has been approved by the FDA for the indication for which the claim is being made, that it is neither experimental nor investigational, and that the use of the product is safe and efficacious, medically necessary, appropriate for the specific patient and cost effective. Since reimbursement by one payor does not guarantee reimbursement by another, we or our licensees may be required to seek approval from each payor individually. Seeking such approvals is a time-consuming and costly process. Third-party payors routinely limit the products that they will cover and the amount of money that they will pay and, in many instances, are exerting significant pressure on medical suppliers to lower their prices. There is significant uncertainty concerning third-party reimbursement for the use of any pharmaceutical product incorporating new technology and we are not sure whether third-party reimbursement will be available for our proposed products once approved, or that the reimbursement, if obtained, will be adequate. There is also significant uncertainty concerning third-party reimbursement for products treating FSD and ED. Less than full reimbursement by governmental and other third-party payors for our proposed products would adversely affect the market acceptance of these proposed products. Further, healthcare reimbursement systems vary from country to country, and we are not sure whether third-party reimbursement will be made available for our proposed products under any other reimbursement system.

Manufacturing and Marketing

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

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

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 cGMPs at acceptable costs. We have identified and contracted with a third-party manufacturer for the production of bremelanotide, and have validated manufacturing of the bremelanotide drug substance under cGMPs. However, we have not negotiated a long-term supply agreement with the third-party manufacturer, and may not be able to enter into a supply agreement on acceptable terms, if at all.

Our PL-6983 product candidate is also a synthetic peptide. We have manufactured PL-6983 in house, but have not contracted with a third-party manufacturer to produce the product 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 cGMPs 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.

If sales of NeutroSpec resume, we will be dependent on DSM N.V. of the Netherlands for the manufacture of the NeutroSpec drug substance and intermediate drug product and on Ben Venue Laboratories of Cleveland, Ohio for the manufacture of the final NeutroSpec drug product. We do not have long-term supply agreements in force with either DSM N.V. or Ben Venue Laboratories, and may not be able to enter into supply agreements on acceptable terms, if at all. The failure to enter into a definitive supply agreement with either could interfere with our ability to deliver NeutroSpec on a timely basis or at all. If sales of NeutroSpec resume, we will rely on our arrangement with Mallinckrodt to market, sell and distribute NeutroSpec. We have limited control over these activities. We package and ship our radiopharmaceutical products in the form of non-radioactive kits. Prior to patient administration, the product is radiolabeled with the specified radioisotope, generally by a specialized radiopharmacy. We do not sell or distribute any radioactive substances.

The failure of any manufacturer or supplier to comply with FDA cGMPs 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 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.

Table of Contents

Product Liability and Insurance

Our business may be affected by potential product liability risks which are inherent in the testing, manufacturing, marketing and use of our proposed products. We have liability insurance providing up to $10.0 million coverage in the aggregate as to certain clinical trial risks.

Employees

As of September 26, 2008, we employed 46 persons full time, of whom 32 are engaged in research and development activities and 14 are engaged in administration and management. 18 of our employees hold Ph.D. or M.D. degrees. 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.

From time to time, we hire 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, clinical management, regulatory strategy and market research. Our independent advisors and consultants sign agreements that provide for confidentiality of our proprietary information and rights to any intellectual property developed while working for us.

Item 1A. Risk Factors.

We expect to 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, 2008, we had an accumulated deficit of approximately $202.6 million. We expect to incur additional losses as we continue our development of PL-3994, bremelanotide, PL-6983 and NeutroSpec. Unless and until we receive approval from the FDA or other equivalent regulatory authorities outside the United States, we cannot sell our products and will not have product revenues from them. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from reimbursements and other contract revenue under collaborative development agreements, existing cash balances and outside sources of financing, which may not be available on acceptable terms, if at all.

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

We expect that our existing cash and cash equivalents, available-for-sale investments and other current assets will not provide sufficient working capital to fund our operations for the next twelve months. In order to maintain our presently anticipated operations, we will need to raise additional funds. In 2007, we were able to raise $25.5 million in net proceeds through the sale of common stock. However, we have substantial ongoing operating expenses associated with the development of our product candidates. As of June 30, 2008, we had cash and cash equivalents of $9.4 million and available-for-sale investments of $3.4 million, with current liabilities of $3.3 million net of the current portion of deferred revenues of $1.7 million. We anticipate receiving a significant milestone payment from AstraZeneca by the end of the first quarter of calendar year 2009, provided we achieve specified objectives by that time, but no assurance can be given that we will achieve the specified objectives by that time.

We may raise additional funds through public or private equity financings, collaborative arrangements on our product candidates or other sources. However, additional funding may not be available on acceptable terms or at all. If adequate funds are not available, we will need to further curtail operations significantly, including the delay, modification or cancelation of operations and plans, including preclinical studies and clinical trials, related to PL-3994, bremelanotide, PL-6983 and NeutroSpec. 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.

Our independent registered public accounting firm has expressed doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

Our consolidated financial statements as of June 30, 2008 have been prepared under the assumption that we will continue as a going concern. Our independent registered public accounting firm has issued a report dated September 26, 2008 that included an explanatory paragraph referring to our recurring net losses and negative cash flows from operations and expressing substantial doubt in our ability to continue as a going concern without additional funds becoming available. Our ability to continue as a going concern is dependent upon our ability to obtain additional equity financing or other capital, attain further operating efficiencies, reduce expenditures, and,

11

Table of Contents

ultimately, to generate revenue. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. We are continually evaluating opportunities to raise additional funds through public or private equity financings, as well as evaluating prospective business partners, and will continue to do so. However, if adequate funds are not available to us when we need it, and we are unable to enter into some form of strategic relationship that will give us access to additional cash resources, we will be required to even further curtail our operations which would, in turn, further raise substantial doubt about our ability to continue as a going concern.

Based upon the recent price of our common stock on the American Stock Exchange (the AMEX), even if we are able to raise additional capital it is likely that our existing stockholders will experience substantial dilution.

If we raise additional capital as we intend, we will almost certainly need to sell a significant amount of equity securities, whether in the form of new shares of common stock or some other form of convertible security, in order to raise any meaningful amount of capital, based upon our recent stock price. Any significant sale of equity securities in any form at these prices will result in significant dilution to our existing stockholders. The prospect of this dilution is likely to continue to have a negative effect on the market price and trading volume of our common stock until such time as an actual financing occurs.

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

Our operations to date have been 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 you to assess our ability to commercialize our product candidates.

We have not yet demonstrated our ability to perform the functions necessary for the successful commercialization of any of our product candidates other than NeutroSpec. The successful commercialization of our other 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;
- 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.

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

- 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

Table of Contents

lack of effectiveness of the product being tested.

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

product approval or clearance;

regulatory compliance;

good manufacturing practices;

intellectual property rights;

product introduction; and

marketing and competition.

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

Government authorities in the United States and other countries extensively regulate the advertising, labeling, storage, record-keeping, safety, efficacy, research, development, testing, manufacture, promotion, marketing and distribution of drug products. Drugs are subject to rigorous regulation by the FDA in the United States 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 preclinical laboratory tests, preclinical studies and formulation studies;

submission to the FDA of an IND, 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, or, for products categorized as biologicals such as NeutroSpec, a BLA; and

FDA review and approval of the NDA or BLA before any commercial marketing or sale.

The results of product development, preclinical studies and clinical studies are submitted to the FDA as part of an NDA or BLA. The NDA or BLA 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. The FDA may refer the NDA or BLA 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. 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 pre- and post-market regulatory standards 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 effect of approved products, 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 levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals.

Satisfaction of FDA pre-market approval requirements for new drugs typically takes several years and the actual time required for approval may vary substantially based upon the type, complexity and novelty of the product or disease. Government regulation may prevent marketing of potential products or delay marketing for a considerable period of time and impose costly procedures upon our activities. 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. Success in early stage clinical trials does not assure success in later stage

clinical trials. Data obtained from clinical activities is not always conclusive and may be susceptible to varying interpretations that could delay, limit or prevent regulatory approval. Even if a product candidate receives regulatory approval, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market.

Table of Contents

If regulatory approval of any of our product candidates is granted, it will be limited to certain disease states or conditions. 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 cGMPs regulations. Failure to comply with the statutory and regulatory requirements subjects the manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, voluntary recall of a product, injunctive action or possible civil penalties. 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. Because we intend to contract with third parties for manufacturing of these products, our ability to control third-party compliance with FDA requirements will be limited to contractual remedies and rights of inspection. Failure of third-party manufacturers to comply with cGMPs or other FDA requirements may result in legal or regulatory action by the FDA.

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.

In order to reintroduce NeutroSpec to the market, we will be required to conduct extensive clinical trials of NeutroSpec, and may not be able to obtain regulatory approval.

We do not anticipate seeking approval to recommence marketing NeutroSpec for the previously approved indication, imaging and diagnosing equivocal appendicitis. The reported serious adverse events were associated with off-label use (use for an indication other than diagnosis of equivocal appendicitis), and substantial sales of NeutroSpec were for off-label uses. We have conducted additional laboratory studies to explore the relationship between NeutroSpec and the reported serious adverse events. However, results of those studies are not conclusive, and we may not be able to develop a sufficient understanding of the relationship to warrant application to the FDA to conduct additional studies. We also may not be able to develop methods, formulations or protocols that permit NeutroSpec to be used safely. We also do not know whether the FDA will concur in our risk/benefit assessment of NeutroSpec, or permit NeutroSpec to be marketed again. Even if we seek to reintroduce NeutroSpec to the market, we anticipate seeking approval to market NeutroSpec for indications, such as osteomyelitis (infection deep inside a bone), which will require that Phase 2 and Phase 3 clinical trials be successfully completed, as to which there can be no assurance, prior to seeking approval of the FDA.

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 government or other healthcare payors; and

advantages over alternative treatment methods.

Because we voluntarily withdrew NeutroSpec from the market, it may be more difficult to gain market acceptance with NeutroSpec, assuming that the FDA permits NeutroSpec to be reintroduced to the market.

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

Table of Contents

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. The competition for these relationships is intense, 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.

The results of our clinical trials may not support our product claims.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay or eliminate our ability to commercialize our product candidates and generate product revenues.

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 PL-3994, bremelanotide, PL-6983 or NeutroSpec. Our contract manufacturers must perform these manufacturing activities in a manner that complies with FDA regulations. 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. Establishing relationships with new suppliers, who must be FDA-approved, is a time-consuming and costly process.

We are subject to extensive regulation in connection with the laboratory practices and the hazardous materials we use.

We are subject to various laws and regulations regarding laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as noted above, the FDA and other regulatory authorities have broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and withdraw approvals, any one or more of which could have a material adverse effect on us. We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Contamination or injury from hazardous materials used in the development of our products could result in a liability exceeding our financial resources.

Our research and development involves the use of hazardous materials and chemicals, including radioactive compounds. We cannot completely eliminate the risk of contamination or injury from these materials. In the event of contamination or injury, we may be responsible for any resulting damages. Damages could be significant and could exceed our financial resources, including the limits of our insurance.

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 PL-3994, an NPRA agonist, for the treatment of heart failure and difficult-to-control hypertension, bremelanotide for prevention of organ damage secondary to cardiac surgery and related indications, and PL-6983 for FSD. 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.

If we recommence sales of NeutroSpec, we will depend on Mallinckrodt, our strategic collaboration partner, to market, sell and distribute the product. If Mallinckrodt fails to adequately market NeutroSpec or devote enough resources to NeutroSpec, our potential revenues will be adversely affected. If Mallinckrodt determines to not

15

Table of Contents

proceed with NeutroSpec, we may have difficulty establishing new marketing relationships, and in any event, we will have limited control over these activities.

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 January 2007 license agreement with AstraZeneca, as amended in June 2008, for our melanocortin-based therapeutic compounds for obesity, diabetes and related metabolic syndrome, we have no direct control over the development of compounds and have only limited, if any, input on the direction of development efforts. If the results of development efforts are negative or inconclusive, AstraZeneca may decide to abandon further development of this program, including terminating the license agreement by giving us notice of termination. Because much of the potential value of the license arrangement with AstraZeneca is contingent upon the successful development and commercialization of the licensed technology, the ultimate value of this license will depend on the efforts of AstraZeneca. If AstraZeneca does not succeed in developing the licensed technology for any reason, or elects to discontinue the development of this program, we may be unable to realize the potential value of this arrangement.

Competing products and technologies may make our proposed products noncompetitive.

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

There are a large number of approved oral and intravenous drugs for control of hypertension, some of which may be used for difficult-to-control hypertension. While PL-3994 is believed to decrease hypertension by a different mechanism than existing approved drugs, we may be required to demonstrate efficacy and safety equivalent or superior to these other products in order to achieve approval and market acceptance.

We are not aware of any FDA-approved product for organ protection that works by the same mechanism as bremelanotide. However, we are aware of one other product in Phase 2 clinical trials that we believe works by the same or a related mechanism, and there are other products and technologies in development for organ protection, including renal protection. In order to achieve approval and market acceptance, bremelanotide may be required to demonstrate efficacy and safety equivalent or superior to these other products and technologies.

There are a number of other products being developed for FSD and ED. We are aware of three oral FDA-approved PDE-5 inhibitor drugs for the treatment of ED. These products are also approved in Europe, Japan and most of the world s pharmaceutical markets. In order to achieve approval and market acceptance, PL-6983 may be required to demonstrate efficacy and safety equivalent or superior to these other products.

We are aware of one company developing a technetium imaging product and another company marketing an antibody-based technetium product in some European countries, both of which may compete with NeutroSpec for certain indications. In addition, other technologies may also be used to diagnose osteomyelitis and other infection-related diseases, including CT and ultrasound technologies.

The biopharmaceutical and diagnostic industries are highly competitive. We are likely to encounter significant competition with respect to PL-3994, bremelanotide, PL-6983 and NeutroSpec. 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 PL-3994, bremelanotide, PL-6983 or NeutroSpec. 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 significant revenues from the sale of our future products will depend, in part, on the ability of healthcare providers to obtain adequate reimbursement from Medicare, Medicaid, private insurers and other healthcare payers.

The continuing efforts of government and insurance companies, health maintenance organizations (HMOs) and other payers of healthcare costs to contain or reduce costs of healthcare may adversely affect our future revenues and ability to achieve profitability. Our ability to successfully commercialize our future products will depend, in significant part, on the extent to which healthcare providers can obtain appropriate reimbursement levels

Table of Contents

for the cost of our products and related treatment. Third-party payers are increasingly challenging the prices charged for diagnostic and therapeutic products and related services. Also, the trend towards managed healthcare in the U.S. and the concurrent growth of organizations such as HMOs could control or significantly influence the purchase of

healthcare services and products. In addition, legislative proposals to reform healthcare or reduce government insurance programs may result in lower prices or the actual inability of prospective customers to purchase our future products. 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.

We could lose our rights to NeutroSpec, which could adversely affect our potential revenues.

Our rights to a key antibody used in NeutroSpec are dependent upon an exclusive license agreement with The Wistar Institute of Biology and Anatomy. This agreement contains specific performance criteria and requires us to pay royalties and make other payments. Failure to meet these requirements, or any other event of default under the license agreement, could lead to termination of the license agreement. If the license agreement is terminated, we will be unable to make or market NeutroSpec, in which case we may lose the value of our substantial investment in developing the product, as well as any future revenues from selling NeutroSpec.

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.

Table of Contents

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 product/medical professional liability insurance, which includes liability insurance for our clinical trials. We, or any corporate collaborators, may not 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 research professionals and third-party contractors and consultants, and the loss of their services could materially adversely affect our business.

We have decreased staffing levels to 46 employees, the minimum that we believe is necessary to execute our currently planned preclinical and clinical programs. We will rely on various contractors and consultants to provide critical services, some of which were previously provided by our employees. Our ability to execute our preclinical and clinical programs depends on our continued retention and motivation of remaining management and scientific personnel, including executive officers and senior members of research, development and management who possess significant technical expertise and experience and oversee our development programs. Our success also depends on our ability to develop and maintain relationships with contractors, consultants and scientific advisors. If we lose the services of existing personnel or fail to attract required new personnel, our development programs could be adversely affected. Competition for personnel is intense. In addition, we will need to hire additional personnel or consultants to increase our research and development activities if we decide to expand research and development on new product opportunities.

Stockholders may experience dilution from the exercise of outstanding options and warrants and the vesting of restricted stock units.

As of June 30, 2008, options and warrants to purchase 11,628,688 shares of common stock were outstanding at various exercise prices ranging from $0.21 per share to $5.13 per share, 1,138,824 shares were issuable under restricted stock units granted to our employees that will vest if the employee remains employed with us through September 30, 2008 or earlier under certain conditions, and 975,000 shares were issuable under restricted stock units to our executive officers that will vest if the named officers remain employed with us through March 26, 2010 or earlier under certain conditions. The issuance or potential issuance of common stock upon the exercise of these options and warrants and vesting of restricted stock units may adversely affect the market price of our common stock and result in substantial dilution to our existing stockholders.

Our stock price is, 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 U.S. and foreign countries;

Table of Contents

economic or other crises and other external factors;

period-to-period fluctuations in our revenue and other results of operations;

changes in financial estimates by securities analysts; and

sales of our common stock.

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

For the year ended June 30, 2008, the price of our stock has been extremely volatile, ranging from a high of $2.09 per share to a low of $0.17 per share. The volatility in our stock price related primarily to our announcement that we delayed initiation of Phase 3 clinical trials of bremelanotide for ED, following responses in late August 2007 from the FDA raising serious concerns about the acceptable benefit/risk ratio to support progression into Phase 3 as a first-line therapy in the general population.

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.

The AMEX and other national stock exchanges maintain standards for initial and continued listing of shares for trading. These standards include requirements for minimum per share stock prices, aggregate market values of shares outstanding, minimum stockholders equity and related factors. We are listed on the AMEX, and continue to meet standards for continued listing. If we are unable to meet these requirements and are delisted, the ability of investors to buy or sell our shares will be restricted, in which case the market value of our common stock and our ability to obtain additional financing on acceptable terms may be adversely affected.

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.

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 power, 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 granted under these plans in the event of a change of control. If we accelerate the vesting of options, 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.

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

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

We have broad discretion over the use of available cash and may not realize an adequate return.

We have considerable discretion in the application of available cash and have not fixed the amounts that we will apply to various corporate purposes, including potential acquisitions. We may use cash for purposes that do not yield a significant return, if any, for our stockholders.

Table of Contents

Item 2. Properties.

Our corporate offices and research and development facilities are located at 4C Cedar Brook Drive, Cedar Brook Corporate Center, Cranbury, NJ 08512, where we lease approximately 28,000 square feet under a lease which expires July 17, 2012. We also lease 10,000 square feet of additional office space and 12,000 square feet of laboratory space in two other buildings in the same center under leases that expire in 2015 and 2012, respectively. The leased properties are in good condition.

Item 3. Legal Proceedings.

We may be 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. Submission of Matters to a Vote of Security Holders.

None.

Table of Contents

PART II

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

The table below provides, for the fiscal quarters indicated, the reported high and low sales prices for the common stock on the AMEX since July 1, 2006.

FISCAL YEAR ENDED JUNE 30, 2008	HIGH	LOW
Fourth Quarter	$0.29	$0.17
Third Quarter	0.46	0.20
Second Quarter	0.47	0.19
First Quarter	2.09	0.39

FISCAL YEAR ENDED JUNE 30, 2007	HIGH	LOW
Fourth Quarter	$2.13	$1.80
Third Quarter	4.00	1.75
Second Quarter	3.03	1.85
First Quarter	2.50	1.71

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

Holders of common stock. On September 26, 2008, we had approximately 257 holders of record of common stock. On September 26, 2008, the closing sales price of our common stock as reported on the AMEX was $0.16 per share.

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

Dividend restrictions. Our outstanding Series A Preferred Stock, consisting of 4,997 shares on September 26, 2008, 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.

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.

In 2004, we entered into a collaborative development and marketing agreement with King Pharmaceuticals, Inc. (King) to jointly develop and commercialize bremelanotide, which agreement was terminated effective December 2007. Deferred revenue related to the King agreement had been recognized as revenue over the estimated period of our performance during the initial development term of this agreement. In connection with the termination of the agreement, we recognized as revenue in our fiscal year ended June 30, 2008 all remaining deferred up-front license fees received from King, together with associated deferred costs, in the amounts of $6.5 million and $0.8 million, respectively.

Table of Contents

Deferred revenue related to the AstraZeneca agreement is being recognized as revenue on a straight-line basis over the maximum period during which we may perform research services under the agreement. If our estimated period of performance is reduced to less than the maximum, the amortization period for any remaining deferred revenue will also be reduced.

Accrued Expenses

A significant portion of our development activities are performed by third parties. 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 model, which requires us to make estimates of volatility and expected option lives. We estimate these factors at the time of grant based on our own prior experience, public sources of information and information for comparable companies. The amount of recorded compensation related to an option grant is not adjusted for subsequent changes in these estimates or for actual experience. The amount of our recorded compensation is also dependent on our estimates of future option forfeitures and the probability of achievement of performance conditions. If we initially over-estimate future forfeitures, our reported expenses will be understated until such time as we adjust our estimate. Changes in estimated forfeitures will affect our reported expenses in the period of change and future periods.

Certain options are subject to periodic re-measurement over the vesting period as services are rendered, based on changes in the fair value of our common stock. The vesting of certain other options is dependent on future events. In addition, 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 and certain changes in our share price. As a result, share-based compensation charges may vary significantly from period to period.

Results of Operations

Year Ended June 30, 2008 Compared to the Year Ended June 30, 2007:

Licenses, Grants and Contracts For the fiscal year ended June 30, 2008 (fiscal 2008), we recognized $11.5 million in licenses, grants and contracts compared to $14.4 million for the fiscal year ended June 30, 2007 (fiscal 2007). Revenue consisted of the following:

Fiscal 2008	Fiscal 2007	Revenue related to:
$8.2 million	$12.9 million	bremelanotide for ED and FSD pursuant to our collaboration agreement with King, which was terminated effective December 2007
$3.0 million	$1.2 million	our license agreement with AstraZeneca
$0.3 million	$0.3 million	NeutroSpec, pursuant to our collaboration agreement with Mallinckrodt.

The fluctuation in revenue related to King primarily reflects the recognition in fiscal 2008 of the remaining deferred license revenue pursuant to King s up-front payment, based on the termination of our collaboration agreement with King. License and contract revenue from AstraZeneca for fiscal 2008 and fiscal 2007 consists of $1.3 million and $0.6 million, respectively, of revenue related to our research services performed during those periods and $1.7 million and $0.6 million, respectively, of license revenue related to AstraZeneca s up-front license fee. Contract revenue from Mallinckrodt primarily reflects Mallinckrodt s share of the costs incurred in NeutroSpec development activities. Future contract revenue from AstraZeneca and Mallinckrodt, in the form of reimbursement of shared development costs or the recognition of deferred license fees, will fluctuate based on development activities in our obesity and NeutroSpec programs. We may also earn contract revenue based on the attainment of development milestones.

Research and Development Research and development expenses decreased to $21.2 million for fiscal 2008 compared to $36.9 million for fiscal 2007.

Research and development expenses related to bremelanotide, primarily for ED and FSD, decreased approximately $15.1 million, from $18.3 million in fiscal 2007 to $3.2 million for fiscal 2008. These amounts

Table of Contents

include both third-party costs incurred by us and partially reimbursed by King and our share of costs for development activities performed by King. Research and development expenses related to bremelanotide for ED and FSD decreased as a result of (i) the completion of certain Phase 2B trials on both men and women, (ii) the decision to not initiate Phase 3 clinical trials for ED, and iii) the strategic restructuring and refocusing of our clinical-stage product portfolio development programs. Similar to the recognition of license revenue explained above, fiscal 2008 includes the recognition of $0.8 million of recorded deferred costs based on the termination of our collaboration agreement with King.

Research and development expenses related to our PL-3994, bremelanotide for prevention of organ damage, PL-6983, obesity, NeutroSpec and other preclinical programs were $3.9 million for fiscal 2008 compared to $4.1 million for fiscal 2007. Spending to date has been primarily related to the identification and optimization of lead compounds, and secondarily to preclinical studies and a Phase 1 and a Phase 2a trial with PL-3994. 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 trial, preclinical and discovery programs, and our ability to progress compounds in addition to PL-3994 into human clinical trials.

The historical amounts of project spending above exclude general research and development spending, which decreased to $14.1 million for fiscal 2008 compared to $14.5 million for fiscal 2007. The decrease is primarily related to the reduction in workforce in September 2007.

Cumulative spending from inception to June 30, 2008 on our bremelanotide, NeutroSpec and other programs (which includes PL-3994, PL-6983, obesity, and other discovery programs) amounts to approximately $120.7 million, $55.4 million and $43.8 million, respectively. Due to various risk factors described in our periodic filings with the SEC, including the difficulty in currently estimating the costs and timing of future Phase 1 clinical trials and larger-scale Phase 2 and Phase 3 clinical trials for any product under development, we cannot predict with reasonable certainty when, if ever, a program will advance to the next stage of development or be successfully completed, or when, if ever, related net cash inflows will be generated.

General and Administrative General and administrative expenses decreased to $6.9 million for fiscal 2008 compared to $7.3 million for fiscal 2007. The decrease is primarily related to the reduction in workforce initiated in September 2007.

Income Tax Benefit Income tax benefits of $1.3 million in fiscal 2008 and $0.8 million in fiscal 2007 relate to the sale of New Jersey state net operating loss carryforwards. The amount of such losses and tax credits that we are able to sell depends on annual pools and allocations established by the state of New Jersey.

Liquidity and Capital Resources

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

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

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

23

Table of Contents

Failure to 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 2008, we used $20.6 million of cash for our operating activities, compared to $22.1 million used in fiscal 2007 and $23.4 million used in fiscal 2006. Net cash outflows from operations in fiscal 2007 were favorably impacted by the receipt of an up-front license payment of $10.0 million from AstraZeneca in January 2007. 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.

In fiscal 2008, net cash used in investing activities amounted to $1.3 million, consisting of $0.3 million used for the acquisition of capital equipment and $1.0 million used to purchase available-for-sale investments, compared to $0.9 million and $0.8 million, respectively, used for the acquisition of capital equipment during fiscal 2007 and fiscal 2006.

For fiscal 2008, net cash used in financing activities amounted to $0.2 million, consisting of $0.3 million in payments on capital lease obligations partially offset by $0.1 million in proceeds from the exercise of common stock warrants. During fiscal 2007, net cash provided by financing activities amounted to $26.0 million, primarily reflecting proceeds from the sale of common stock in a registered offering in February 2007. During fiscal 2006, net cash provided by financing activities was $36.9 million and included proceeds from the sale of common stock and warrants to King in September 2005 and the sale of common stock and warrants in an April 2006 offering.

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, 2008, our cash and cash equivalents were $9.4 million and our available-for-sale investments were $3.4 million. Our existing cash, cash equivalents and available-for-sale investments are not sufficient to fund our planned operations for the next twelve months. This raises substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that we continue as a going concern.

We intend to seek additional capital through public or private equity financings, collaborative arrangements on our product candidates, milestone payments or other sources. We anticipate receiving a significant milestone payment from AstraZeneca by the end of the first quarter of calendar year 2009, provided we achieve specified objectives by that time. However, additional funding may not be available on acceptable terms or at all. If adequate funds are not available, we will further curtail operations significantly, including the delay, modification or cancelation of product candidate development plans and further decreases in staffing levels. We may also be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available, and relinquish, license or otherwise dispose of rights on unfavorable terms to technologies and product candidates that we would otherwise seek to develop or commercialize ourselves.

The nature and timing of our development activities are highly dependent on our financing activities. No assurance can be given that we will earn future milestone payments that are contingent on specified events or that we will not consume a significant amount of our available resources before that time. We plan to continue to monitor the progress of our development programs and the timing and amount of related expenditures and potential milestone receipts, refine our operations, control expenses, evaluate alternative methods to conduct our business and seek additional financing and sharing of development costs through strategic collaboration agreements or other resources.

Future capital requirements will also depend on the extent to which we acquire or invest in businesses, products and technologies or sell or license our product candidates to others. If we are successful in identifying a product or technology for acquisition, we may require substantial funds for such an acquisition and subsequent development or commercialization. We do not know whether any acquisition will be consummated in the future or whether we will be able to obtain additional funding if we identify such an acquisition.

We anticipate incurring additional losses over at least the next few years. To achieve profitability, 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.

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, 2008:

24

Table of Contents

	Payments due by Period				
	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Facility operating leases	$ 9,208,329	$ 2,115,527	$ 4,341,056	$ 2,290,236	$ 461,510
Capital lease obligations	421,924	291,011	116,070	14,843	-
License agreements	240,000	15,000	30,000	30,000	165,000
Total contractual obligations	$ 9,870,253	$ 2,421,538	$ 4,487,126	$ 2,335,079	$ 626,510

Our license agreements also include royalty and other contingent payment obligations and may be terminated by us under certain conditions.

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

Table of Contents

Item 8. Financial Statements and Supplementary Data.

Table of Contents
Consolidated Financial Statements

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

Table of Contents (Financial)

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 (the Company) as of June 30, 2008 and 2007, and the related consolidated statements of operations, cash flows, and stockholders equity for each of the years in the three-year period ended June 30, 2008. 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, 2008 and 2007, and the results of their operations and their cash flows for each of the years in the three-year period ended June 30, 2008, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring net losses and negative cash flows from operations and will require substantial additional financing to continue to fund its development activities. These conditions raise substantial doubt about its ability to continue as a going concern. Management s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

Philadelphia, Pennsylvania
September 26, 2008

Table of Contents (Financial)

PALATIN TECHNOLOGIES, INC.

Consolidated Balance Sheets

	June 30, 2008	June 30, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,421,770	$ 31,447,615
Available-for-sale investments	3,352,771	2,323,642
Accounts receivable	5,747	607,841
Prepaid expenses and other current assets	484,362	1,008,464
Total current assets	13,264,650	35,387,562
Property and equipment, net	5,128,076	6,070,226
Restricted cash	475,000	475,000
Other assets	257,198	848,446
Total assets	$ 19,124,924	$ 42,781,234
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Capital lease obligations, current portion	$ 263,128	$ 216,841
Accounts payable	635,183	1,120,894
Accrued expenses	1,666,628	2,420,837
Accrued compensation	767,509	941,300
Deferred revenue, current portion	1,666,669	4,864,833
Total current liabilities	4,999,117	9,564,705
Capital lease obligations, net of current portion	121,629	275,126
Deferred rent, net of current portion	1,479,794	1,966,628
Deferred revenue, net of current portion	5,972,220	12,443,087
Total liabilities	12,572,760	24,249,546
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock of $0.01 par value - authorized 10,000,000 shares; Series A Convertible; issued and outstanding 4,997 shares as of June 30, 2008 and 2007, respectively	50	50
Common stock of $0.01 par value - authorized 150,000,000 shares; issued and outstanding 85,524,077 and 85,126,915 shares as of June 30, 2008 and 2007, respectively	855,241	851,269
Additional paid-in capital	208,247,194	205,875,438
Accumulated other comprehensive income	29,117	-
Accumulated deficit	(202,579,438)	(188,195,069)
Total stockholders' equity	6,552,164	18,531,688
Total liabilities and stockholders' equity	$ 19,124,924	$ 42,781,234

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

Table of Contents (Financial)

PALATIN TECHNOLOGIES, INC.

Consolidated Statements of Operations

	Year Ended June 30,		
	2008	**2007**	**2006**
REVENUES:			