

PALATIN TECHNOLOGIES INC  
Form 10-K  
September 13, 2007

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

**FORM 10-K**

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the fiscal year ended June 30, 2007

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 001-15543

\_\_\_\_\_

**PALATIN TECHNOLOGIES, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**95-4078884**

(I.R.S. Employer Identification No.)

**4C Cedar Brook Drive**

**Cranbury, New Jersey**

(Address of principal executive offices)

**08512**

(Zip Code)

**(609) 495-2200**

(Registrant's telephone number, including area code)

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

<b>Title of Each Class</b>	<b>Name of Each Exchange on Which Registered</b>
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

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

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

Indicate by check mark 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.



## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates, computed by reference to the price at which the common 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, 2006): \$173,816,505.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date (September 4, 2007): 85,204,169.

### **Documents Incorporated by Reference**

Portions of the registrant's proxy statement relating to its Annual Meeting of Stockholders, to be filed within 120 days of its June 30, 2007 fiscal year end are incorporated by reference into Part III of this Annual Report on Form 10-K.

---

**PALATIN TECHNOLOGIES, INC.  
TABLE OF CONTENTS**

		<u>Page</u>
PART I		
Item 1.	<u>Business</u>	2
Item 1A.	<u>Risk Factors</u>	9
Item 1B.	<u>Unresolved Staff Comments</u>	16
Item 2.	<u>Properties</u>	17
Item 3.	<u>Legal Proceedings</u>	17
Item 4	<u>Submission of Matters to a Vote of Security Holders</u>	17
PART II		
Item 5.	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	18
Item 6.	<u>Selected Financial Data</u>	20
Item 7.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	21
Item 7A.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	26
Item 8.	<u>Financial Statements and Supplementary Data</u>	27
Item 9.	<u>Changes In and Disagreements With Accountants on Accounting and Financial Disclosure</u>	46
Item 9A.	<u>Controls and Procedures</u>	46
Item 9B.	<u>Other Information</u>	47
PART III		
Item 10.	<u>Directors, Executive Officers and Corporate Governance</u>	48
Item 11.	<u>Executive Compensation</u>	48
Item 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	48
Item 13.	<u>Certain Relationships and Related Transactions, and Director Independence</u>	48
Item 14.	<u>Principal Accountant Fees and Services</u>	48
PART IV		
Item 15.	<u>Exhibits and Financial Statement Schedules</u>	49
<u>SIGNATURES</u>		

Table of Contents

**PART I**

**Item 1. Business.**

**Forward-looking statements**

Statements in this Annual Report on Form 10-K, 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 on Form 10-K do not constitute guarantees of future performance. Investors are cautioned that statements which are not strictly historical statements contained in this Annual Report on Form 10-K, 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.

**Overview**

We are a biopharmaceutical company focused on discovering and developing targeted, receptor-specific small molecule and peptide therapeutics. Our proprietary drug development pipeline is based primarily on melanocortin (MC)-based therapeutics, and we believe we are a leader in this area of pharmaceutical research and development. Therapeutics affecting the activity of the MC family of receptors may have the potential to treat a variety of conditions and diseases, including sexual dysfunction, obesity and related disorders, cachexia (extreme wasting, generally secondary to a chronic disease), skin pigmentation disorders and inflammation-related diseases.

Bremelanotide is our nasally administered MC-based peptide in clinical development for two distinct indications, the treatment of male erectile dysfunction (ED) and the treatment of female sexual dysfunction (FSD). In 2004, we entered into a collaborative development and marketing agreement with King Pharmaceuticals, Inc. (King) to jointly develop and commercialize bremelanotide. Pursuant to the agreement, we and King shared all collaboration development costs based on an agreed percentage. In September 2007, we received notice from King terminating the agreement in accordance with its terms effective December 5, 2007. Termination followed comments by the U.S. Food and Drug Administration (FDA) raising serious concerns about the acceptable benefit/risk ratio to support the progression of bremelanotide into Phase 3 studies for ED as a first-line therapy in the general population. Upon termination, we will solely own all rights to bremelanotide.

In January 2007, we entered into an exclusive global licensing and research collaboration agreement with AstraZeneca AB (AstraZeneca), a major international pharmaceutical and healthcare business, to discover, develop and commercialize small molecule compounds that target MC receptors for the treatment of obesity, diabetes and related metabolic syndrome. The collaboration is based on Palatin's MC receptor obesity program and includes access to compound libraries, core technologies and expertise in MC receptor drug discovery and development. We and AstraZeneca are in the process of identifying clinical candidate MC therapeutic small molecules for the treatment of obesity and related disorders.

We have developed a library of novel natriuretic (promoting sodium excretion) receptor compounds, and have identified a lead clinical candidate for which we have completed preclinical studies and are preparing an Investigational New Drug (IND) application for starting clinical trials for the treatment of congestive heart failure (CHF). We are also conducting research to identify additional clinical candidate compounds for the treatment of both chronic CHF and acutely decompensated (rapidly deteriorated) CHF.

We are evaluating future development and marketing activities involving NeuroSpec, our radiolabeled monoclonal antibody product for imaging and diagnosing infection, with the Mallinckrodt division of Covidien (Mallinckrodt), with whom we have a strategic collaboration agreement. In December 2005, we and Mallinckrodt voluntarily suspended the sales, marketing and distribution of NeuroSpec following certain serious adverse events involving patients who received NeuroSpec. NeuroSpec was approved for marketing for imaging and diagnosing equivocal appendicitis by the FDA in July 2004.

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 investigating; expanding our pipeline through the utilization of our MC expertise and patented



Table of Contents

drug discovery platform; acquiring synergistic products and technologies; and partially funding our development and discovery programs with the cash flow from our collaboration agreements.

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 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 therein or connected thereto shall not be deemed to be incorporated into this annual report on Form 10-K.

**Products and Technologies in Research and Development**

**ED and FSD Bremelanotide.** Bremelanotide is a patented, nasally administered peptide in clinical development for the treatment of both ED and FSD. Bremelanotide, an MC receptor-based agonist (which promotes a biologic function response) therapeutic, is a synthetic analog of the naturally occurring hormone alpha-MSH (melanocyte-stimulating hormone).

ED is the consistent inability to attain and maintain an erection sufficient for sexual intercourse. The condition is correlated with increasing age, cardiovascular disease, hypertension, diabetes, hyperlipidemia and smoking. In addition, certain prescription drugs and psychogenetic issues may contribute to ED. According to the Massachusetts Male Aging Study, more than 50% of men aged 40-70 report episodes of ED and more than 30 million men in the United States may be afflicted with some form of ED, with less than 20% seeking treatment. The incidence of ED increases with age. Studies show that chronic ED affects about 5% of men in their 40s and 15% to 25% of men by the age of 65. The current market size for ED is more than \$2.5 billion per year.

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. There is tremendous competition to develop, market and sell drugs for the treatment of ED and FSD.

Bremelanotide is the first compound to enter clinical trials in a new drug class, MC receptor agonists, under development to treat sexual dysfunction. Our research suggests that bremelanotide works through activation of MC receptors in the central nervous system, which is a different mechanism of action from currently marketed ED therapies that act directly on the vascular system. As a result, it may offer therapeutic benefits over currently marketed products. The current ED market is primarily served by the PDE-5 inhibitors Viagra®, a brand of sildenafil, Levitra®, a brand of vardenafil, and Cialis®, a brand of tadalafil. A significant portion of ED patients are contraindicated for, or non-responsive to, PDE-5 inhibitors.

We have conducted clinical trials on a nasal formulation of bremelanotide, administered as a single spray in one nostril, which results in a rapid onset of action. We have completed various Phase 1 safety trials and Phase 2A and Phase 2B efficacy clinical trials in male subjects and patients. Two recently completed Phase 2B clinical trials evaluated the safety and efficacy of bremelanotide in patients suffering from mild to severe ED, with one trial limited to non-diabetic patients, and the other to diabetic patients. Both trials, conducted at clinical trial sites throughout the United States, involved an at home, three-month treatment period and evaluated a range of bremelanotide intranasal doses, safety, treatment duration and patient populations.

We have delayed initiation of Phase 3 clinical trials 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. The FDA questioned overall efficacy results and the clinical benefit of bremelanotide in both general and diabetic populations, citing blood pressure increases as its greatest safety concern.

We are reviewing the FDA's comments in the context of our bremelanotide program to determine next steps. The FDA indicated it was amenable to proposals for a different drug development pathway, such as for a second-line therapy for ED in non-responders to approved PDE-5 inhibitors.

We have completed Phase 1 safety trials in female subjects and Phase 2A and Phase 2B efficacy clinical trials in female patients with FSD. The Phase 2A trial included both pre-menopausal and post-menopausal FSD patients, and showed, in both patient populations, an increase in the level of sexual desire and genital arousal in subjects receiving bremelanotide compared to subjects receiving placebo. The Phase 2B trial also included both pre-menopausal and post-menopausal FSD patients, with an at home two-month treatment period. We are in the process of evaluating the results from this Phase 2B trial, and anticipate releasing further information in the second half of calendar 2007.





Table of Contents

**Collaborative Development and Marketing Agreement with King.** In August 2004, we entered into a collaboration agreement with King to jointly develop and commercialize bremelanotide. Pursuant to the terms of the agreement, we and King shared all collaboration development and marketing costs based on an agreed percentage.

Following the decision to delay Phase 3 clinical trials for ED, we received notice from King terminating the agreement in accordance with its terms effective December 5, 2007. Upon termination, we will solely own all rights to bremelanotide, without any financial obligation to King.

**Obesity.** We have an active development program for MC receptor-targeted small molecule 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 MC receptors have a role in eating behavior and energy homeostasis, and that MC receptor agonists, such as alpha-MSH, 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. In the United States, approximately 65 percent of adult Americans are categorized as being overweight or obese. Each year, obesity causes at least 300,000 excess deaths in the United States, and healthcare costs of American adults with obesity amount to approximately \$100 billion. Additionally, studies in adolescents indicate that there is a trend towards increased prevalence of the disease.

MC receptor agonists are also involved in other physiological responses, including sexual response. MC receptor agonists with potential for use in the treatment of obesity generally induce a sexual response. To our knowledge, there are no reports in the scientific literature of MC receptor-target compounds which are effective in animal or human studies for the treatment of obesity and which do not induce a sexual response.

We have developed a class of small molecule compounds targeting MC receptors which are effective in the treatment of obesity in animal models but which do not induce a 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. We believe that we have developed approaches that allow us to differentiate MC receptor-targeted compounds useful for treating obesity and related disorders from compounds that induce a sexual response.

**Research Collaboration and License Agreement with AstraZeneca.** We have an exclusive global licensing and research collaboration agreement with AstraZeneca to discover, develop and commercialize small molecule compounds that target MC receptors for the treatment of obesity, diabetes and related metabolic syndrome. Pursuant to the terms of the agreement, we received an upfront 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, and royalties on sales of approved products. 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.

**Congestive Heart Failure.** We have a program for developing compounds that mimic natural peptides ( peptidomimetics ) for the treatment of CHF. CHF is an illness in which the heart is unable to pump blood efficiently, and includes acutely decompensated CHF with dyspnea (shortness of breath) at rest or with minimal activity. Endogenous (naturally produced) natriuretic peptides have a number of beneficial results, including vasodilation (relaxation of blood vessels), natriuresis (excretion of sodium), and diuresis (excretion of fluids). One product is commercially available in the United States, Natrecor®, a brand of nesiritide, which is a recombinant (genetically made) form of human B-type natriuretic peptide. However, Natrecor® is approved only for use in acutely decompensated CHF with administration by intravenous injection, typically limiting administration to a hospital setting.

CHF directly affects nearly five million people in the United States, with over 500,000 new cases diagnosed each year. Annual medical treatment costs for CHF, which frequently involves expensive hospitalization and therapies, are estimated at over \$25 billion.

Table of Contents

We have developed a library of novel peptidomimetic natriuretic agonists. Certain of these compounds have demonstrated efficacy in animal models when administered by subcutaneous (under the skin) injection. These compounds remain active in animal models for longer periods than do natural or recombinant natriuretic peptides.

We have identified a clinical candidate drug for the treatment of CHF. The drug will be initially evaluated in a subcutaneous form, primarily for the treatment of chronic CHF. We believe that a subcutaneous form of peptidomimetic compound could be used in a clinic or doctor's office, and would not be limited to use in hospitals or specialized medical facilities. We have completed toxicity testing and other preclinical studies with the clinical candidate drug in preparation for filing an IND, and anticipate filing the IND in the second half of calendar 2007. We are also developing an intravenous form of the peptidomimetic compound for acutely decompensated CHF.

**MIDAS Drug Development Platform.** Our obesity and other early-stage programs derived lead compound series by utilizing our MIDAS (Metal Ion-induced Distinctive Array of Structures) proprietary platform technology to design and synthesize novel molecules that mimic the activity of peptides. MIDAS uses metal ions to fix the three-dimensional configuration of peptides, forming conformationally rigid molecules that remain folded specifically in their active forms. These MIDAS molecules are simple to synthesize, are chemically and proteolytically stable, and have the potential to be orally bioavailable. Unlike most other drug discovery approaches, MIDAS can be used to generate both receptor antagonists (which block a normal biological metabolic response) and agonists. 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.

Generation of commercially viable protein and peptide drug molecules with desirable properties continues to be arduous, expensive and labor-intensive. We believe that our MIDAS technology simplifies the development process by eliminating many of the inherent limitations associated with peptides and proteins.

**NeuroSpec®.** NeuroSpec, our trade name for technetium (99m Tc) fanolesomab, includes an anti-CD 15 monoclonal antibody which selectively binds to a type of white blood cell, neutrophils, involved in the immune response. When labeled with the radioactive tracer technetium and injected into the blood stream, the antibody binds to neutrophils accumulated at the 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 NeuroSpec 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 NeuroSpec for off-label uses. In December 2005, the FDA informed Mallinckrodt and us that it had reconsidered the risk/benefit assessment of NeuroSpec and determined that the product should not be administered to patients, until a further understanding and review of the relationship between NeuroSpec and reported serious adverse events is complete. Together with Mallinckrodt, we are reviewing data and assessing approaches for understanding the relationship between NeuroSpec use and the observed serious adverse events. All ongoing clinical trials and plans for future clinical trials and regulatory approvals of NeuroSpec have been suspended and no final decision concerning future activities involving NeuroSpec has been made. We anticipate making a decision on whether to seek to proceed with NeuroSpec in the second half of calendar 2007.

**Strategic Collaboration Agreement with Mallinckrodt.** Mallinckrodt has exclusive worldwide marketing and distribution rights to NeuroSpec under our collaboration agreement. We are responsible for the manufacture of NeuroSpec and Mallinckrodt agreed to pay us a transfer price on each product unit sold to Mallinckrodt and a royalty on their net sales of NeuroSpec. If NeuroSpec 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 NeuroSpec to the market or meet development or sales objectives.

**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. 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.



Table of Contents

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.

There are currently three FDA-approved PDE-5 drugs for ED in the United States and these products are also approved in major foreign markets. We are aware of several products in clinical development for both ED and FSD. We cannot assure you that our competitors will not succeed in developing products that are more effective than any that we are developing. We believe that our ability to compete in the sexual dysfunction market depends on a number of factors including the success and timeliness with which we complete FDA trials, the breadth of indications, if any, for which our products receive approval, and the effectiveness, cost, safety and ease of use of bremelanotide in comparison to the products of our competitors.

There are several FDA-approved drugs for the treatment of obesity, and a large number of products in clinical development by others, including products which target MC receptors. Clinical trials for obesity are lengthy, time-consuming and expensive, and we may not be able to proceed if AstraZeneca terminates our January 2007 license agreement.

One natriuretic peptide product is approved by the FDA and is marketed by a major pharmaceutical company, and another natriuretic peptide product is approved and marketed in Japan. There are a number of other FDA-approved products for the treatment of CHF, and products in preclinical or clinical development by other companies.

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 aggressively seek patent protection for our technology and products in the United States and in those foreign countries where protection is important to the development of our business.

We own issued United States and foreign patents covering bremelanotide, and additionally have pending United States and foreign applications. The claims of issued patents covering bremelanotide may not provide meaningful protection. In addition, third parties may challenge the validity or scope of any issued patent. We also license certain patents relating to compounds and methods of treatment for sexual dysfunction, and believe these patents have value but are not required to commercialize bremelanotide.

We have a number of United States and foreign patent applications relating to our obesity and CHF programs. 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 claims will be allowed.

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 is dependant on 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 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 bremelanotide or NeutroSpec or by our methods of making bremelanotide and NeutroSpec, 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 we do not obtain a license under any such patents, are found liable for infringement, or if such patents are not found to be invalid, 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 or 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.

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. At the time of its initial approval, the FDA required specific future studies for NeutroSpec, and if we seek to reintroduce NeutroSpec, we will have to comply with this requirement. Additionally, if we seek to market NeutroSpec for new indications, we will need to successfully complete Phase 2 and 3 clinical trials prior to making an application to market NeutroSpec for those indications.

In addition to obtaining approval of either a biologics license application or new drug application 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 depend on contract manufacturing establishments, both in the United States and in foreign countries, to manufacture NeutroSpec and bremelanotide. We anticipate that collaborators, licensees or contract manufacturers will also manufacture our proposed obesity and CHF products.

**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 and the use of the product is safe and efficacious, neither experimental nor investigational, 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

Table of Contents

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 ED and FSD. 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.

Ourbremelanotide product is a synthetic peptide. While the production process involves well-established technology, there are limited 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. We currently contract with third-party manufacturers for the production of peptides and have identified a commercial-scale manufacturer.

Our CHF program utilizes peptidomimetic molecules. We are in the process of evaluating potential manufacturers, but have not yet identified commercial-scale manufacturers.

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. The failure of either of these manufacturers to comply with FDA cGMPs or to perform, on a timely basis or at all, 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 suppliers, any of whom must be FDA-approved, is a time-consuming and costly process. 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.

**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 4, 2007, we employed 90 persons full time, of whom 73 are engaged in research and development activities and 17 are engaged in administration and management. Twenty-seven of our employees hold Ph.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 and regulatory approval. 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.

Table of Contents

**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. We expect to incur additional losses as we continue our development of bremelanotide and our other product candidates. Unless and until we receive approval from the FDA or other equivalent regulatory authorities outside the United States, we cannot sell our products and will not have product revenues from them. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from reimbursements and other contract revenue under collaborative development agreements, existing cash balances and outside sources of financing, which may not be available on acceptable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical and clinical trials or obtain approval of our product candidates from the FDA or other regulatory authorities. In addition, we could be forced to suspend or discontinue our product development programs and forego attractive business opportunities, which would have a material adverse effect on our business.

**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 pre-clinical and clinical studies and formulating and manufacturing 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 pre-clinical 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, or to successfully commercialize any products for which we receive regulatory approval, we may not be able to recover our investment in our development efforts.

**Development and commercialization of our proposed products 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 products will require significant further research, development and testing before we can seek regulatory approval to market and sell them.

We must demonstrate that our products 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 drug 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 products. 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

lack of effectiveness of the product being tested.

Table of Contents

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 pre-clinical laboratory tests, pre-clinical trials 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 human clinical trials to establish the safety and efficacy of the drug for each proposed indication;
- submission to the FDA of a new drug application, or NDA, or, for products categorized as biologicals such as NeutroSpec, a biological license application, or BLA; and
- FDA review and approval of the NDA or BLA before any commercial marketing or sale.

The results of product development, pre-clinical 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 an 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 drug 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 value 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 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.

If regulatory approval of any of our products 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

Table of Contents

review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing regulatory requirements, including the FDA's cGMP 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 cGMP or other FDA requirements may result in legal or regulatory action by the FDA.

Outside the United States, our ability to market our products 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.

**We may not be able to obtain regulatory approval to reintroduce NeutroSpec to the market, and may be required to conduct extensive clinical trials prior to regulatory approval.**

NeutroSpec was initially approved by the FDA for imaging of patients with equivocal signs and symptoms of appendicitis. However, 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 are conducting additional laboratory studies to understand the relationship between NeutroSpec and reported serious adverse events. We may not be able to develop a sufficient understanding of the relationship to warrant application to the FDA to conduct additional studies or remarket the product. We may also 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 may seek approval to market NeutroSpec for other indications, such as osteomyelitis (infection deep inside a bone), which will require that Phase 2 and Phase 3 clinical trials be successfully completed 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 bremelanotide is approved only for limited indications, such as for a second-line therapy for ED in non-responders to approved PDE-5 inhibitors, the degree of market acceptance will be necessarily limited.

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

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



Table of Contents

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 pre-clinical 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 pre-clinical 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 bremelanotide, NeutroSpec or our other product candidates. 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 upon 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 bremelanotide for ED and FSD and a product for the treatment of CHF. We do not have marketing partners for either product. If either product is 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. There can be no assurance that we will be able to enter into suitable agreements on acceptable terms.

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 the arrangement with Mallinckrodt fails, we may have difficulty establishing new marketing relationships, and in any event, we will have limited control over these activities.

Table of Contents

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

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 addition, other products are being developed for ED and FSD. In order to achieve approval and market acceptance, bremelanotide may potentially 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 appendicitis, osteomyelitis and other infection-related diseases, including CT and ultrasound technologies.

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

The biopharmaceutical and diagnostic industries are highly competitive. We are likely to encounter significant competition with respect to bremelanotide, NeutroSpec and our other potential products. Many 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 may. These competitive products or technologies may be more effective and useful or less costly than bremelanotide, NeutroSpec or our other potential products. 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 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:

Table of Contents

the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;

if and when patents will be issued;

whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; and

whether we will need to initiate litigation or administrative proceedings, which may be costly whether we win or lose.

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

obtain licenses, which may not be available on commercially reasonable terms, if at all;

redesign our products or processes to avoid infringement;

stop using the subject matter claimed in the patents held by others;

pay damages; or

defend litigation or administrative proceedings, which may be costly whether we win or lose, and which could result in a substantial diversion of our management resources.

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

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

**We 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 arrangement with AstraZeneca for our MC-based therapeutic compounds for obesity, diabetes and related metabolic syndrome, we have no direct control over the development of these drug candidates 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 elect to defer or abandon further development of this program. 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.

**Our collaboration agreements may fail or be terminated unexpectedly, which could result in significant delays and substantial increases in the cost of our research, development and the commercialization of our potential products.**

We are a party to various arrangements with academic, governmental and other corporate partners. The successful development and commercialization of the potential products covered by these arrangements will depend upon the ability of these third parties to fully perform their contractual responsibilities. If any of these parties breaches or unexpectedly terminates their agreement with us, or otherwise fails to conduct their activities in a timely manner, the development or commercialization of our potential products may be delayed.

We intend to enter into additional collaborations to develop and commercialize our potential products in the future. We may not be able to negotiate these arrangements on favorable terms, if at all, and these relationships may not be successful. In addition, our collaborative partners may pursue alternative technologies or develop alternative compounds designed to treat the same diseases that are the subject of their



collaborative programs with us.

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

Table of Contents

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 and senior research professionals.**

We are a relatively small company. Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel, including executive officers and senior members of management that oversee our development programs. In addition, certain research personnel possess significant technical expertise and experience relevant to our development programs and we will need to hire additional personnel to expand our research and development activities. Our success also depends on our ability to develop and maintain relationships with consultants and scientific advisors. Competition for personnel is intense. If we lose the services of existing personnel or fail to attract required new personnel, our development programs could be adversely affected.

**If we acquire other products, technologies or operations, we will incur a variety of risks that could adversely affect our current business operations.**

We are, and expect to continue, actively searching for certain products and technologies to license or acquire, now or in the future. 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. Any such acquisition may expose us to additional risks, including the need to devote significant resources to new activities and to raise additional funds.

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

As of June 30, 2007, options and warrants to purchase 15,338,686 shares of common stock were outstanding at various exercise prices ranging from \$1.00 per share to \$7.75 per share and 975,000 shares were issuable under restricted stock units that will vest if shares of our common stock trade at certain share prices. 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 or result in substantial dilution to our existing stockholders.

**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.

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

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

### Table of Contents

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 pre-clinical or clinical trials or unsatisfactory design or result of these trials;
- 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;
- 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.

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 American Stock Exchange 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 and/or aggregate market values of shares outstanding. 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.

#### **We expect to sell additional equity securities, which will cause dilution.**

We expect to sell more equity securities in the future to obtain cash for operations. We may sell these securities at a discount to the market price. Any future sales of equity will dilute the holdings of existing stockholders, possibly reducing the value of their investment.

#### **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 any future earnings 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.**

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

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.

### **Item 1B. Unresolved Staff Comments**

None.

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 2008, respectively. The leased properties are in good condition.

**Item 3. Legal Proceedings.**

Competitive Technologies, Inc. ( CTI ) initiated arbitration proceedings with us on June 6, 2006 before the American Arbitration Association asserting breach of the terms of our license agreement for patent rights related to certain compounds and methods of treatment for sexual dysfunction and for other actions asserted to arise out of the license agreement. CTI alleged that we committed certain tortious acts against CTI, including fraud and negligent misrepresentation relating to entering into the license agreement originally and tortious interference with business expectancy concerning termination by us and King of the sublicense of the CTI license agreement to King and also seeks a declaration that bremelanotide is covered by the license agreement. CTI is seeking unspecified damages in excess of \$500,000. We filed a reply to CTI's statement of claim, denying all material allegations asserted by CTI, and asserting counterclaims against CTI for declaratory judgment that claims are barred by the previous settlement agreement with CTI and that bremelanotide is not subject to the license agreement with CTI. The license agreement provides for binding arbitration as the remedy for dispute resolution. Motions for summary adjudication of certain claims have been filed by us and CTI, and limited discovery has been conducted relating to the motions. Oral argument on the motions for summary adjudication is scheduled in the second half of calendar 2007, with a hearing on the merits, if required, currently scheduled for the first half of calendar 2008.

CTI also initiated litigation against us on September 16, 2005 by filing a suit in Connecticut Superior Court for breach of the settlement agreement of an earlier arbitration between CTI and us. CTI generally asserted that we failed to timely register for resale shares of our common stock valued at approximately \$300,000 issued to CTI in the settlement, and additionally asserted claims for breach of implied warranties, unfair trade practices, fraudulent inducement, fraudulent non-disclosure and fraud. We denied all material allegations of CTI's claims and asserted defenses and counterclaims against CTI for fraud, fraudulent inducement, unfair trade practices, breach of the settlement agreement and declaratory judgment that under the settlement we were released from any further obligations to CTI relating to payments we may receive from King concerning bremelanotide, that CTI should be compelled to comply with the settlement agreement and withdraw its earlier arbitration request, or alternatively that the settlement agreement of the earlier arbitration should be set aside. CTI filed a reply generally denying our counterclaims and asserting defenses. Discovery has been initiated by both CTI and us.

We cannot reasonably predict the outcome of the disputes with CTI or reasonably estimate the range of potential loss, if any. Although the amount of any liability that could arise with respect to these matters cannot be predicted, we do not believe that the resolution of these matters will have a material adverse effect on our financial position, results of operations or liquidity.

**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 American Stock Exchange (the AMEX) since July 1, 2005.

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

FISCAL YEAR ENDED JUNE 30, 2006	HIGH	LOW
Fourth Quarter	\$2.88	\$1.95
Third Quarter	3.72	2.67
Second Quarter	4.03	1.96
First Quarter	2.36	1.85

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 4, 2007, we had approximately 240 holders of record of common stock. On September 4, 2007, the closing sales price of our common stock as reported on the AMEX was \$0.67 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 4, 2007, 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.

*Stock performance graph.* The following graph compares the yearly change in the cumulative total shareholder return on our common stock with the cumulative total return on the Nasdaq Composite Index and the Nasdaq Biotechnology Index for the last five fiscal years, ending June 30, 2007. The graph assumes the investment of \$100 in each stock or index on June 30, 2002, and the reinvestment of any dividends (we have never paid a dividend).

Table of Contents

*Securities authorized for issuance under equity compensation plans.*

**Equity Compensation Plan Information  
as of June 30, 2006**

<u>Plan category</u>	Number of securities to be issued upon exercise of outstanding options, warrants and <u>rights</u> (a)	Weighted-average exercise price of outstanding options, warrants <u>and rights</u> (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities <u>reflected in column (a)</u> ) (c)
Equity compensation plans approved by security holders	6,388,654 (1)	\$2.89 (1)	2,795,777
Equity compensation plans not approved by security holders	646,967	1.84	0
<b>Total</b>	<b>7,035,621</b>		<b>2,795,777</b>

(1) Excludes an aggregate of 975,000 shares issuable upon vesting of restricted stock units. Restricted stock units will vest in 325,000-share increments if our closing share price is greater than \$4.00, \$6.00 and \$8.00 for twenty consecutive trading days.

We have authorized the issuance of equity securities under the compensation plans described below, without the approval of stockholders.

Richard J. Murphy Stock Option Agreement, dated December 4, 1997: provided stock options to a former director to purchase 5,000 shares at \$5.44 per share and 1,066 shares at \$7.50 per share, with an expiration date of December 4, 2007. These options replaced options for the same number of shares at the same prices which terminated under our 1996 Stock Option Plan.

Wistar Institute of Anatomy and Biology warrants, dated December 15, 2000: provided common stock purchase warrants to a technology licensor to purchase 15,000 shares at \$4.00 per share, with an expiration date of December 15, 2010.

Wistar Institute of Anatomy and Biology warrants, dated May 13, 2002: provided common stock purchase warrants to a technology licensor to purchase 15,000 shares at \$2.82 per share, with an expiration date of May 13, 2012.

North Coast Securities Corporation warrants, dated November 30, 2004: provided common stock purchase warrants to an advisor to purchase 50,000 shares at \$2.97 per share and 25,000 shares at \$3.38 per share, with an expiration date of November 30, 2007.

Placement warrants: provided common stock purchase warrants as compensation to various private offering placement agents to purchase an aggregate of 535,901 shares. These warrants have the following share amounts, exercise prices (rounded to the nearest cent) and expiration dates:

<u>Offering</u>	<u>Shares Purchasable</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
July 2002	51,502	\$1.46	07-29-07
July 2002	25,752	\$1.37	07-29-07
Fall 2002	458,647	\$1.54	11-15-07

Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

Table of Contents

**Item 6. Selected Financial Data.**

The following selected consolidated financial data has been derived from the audited consolidated financial statements of Palatin Technologies, Inc. This data should be read in conjunction with our consolidated financial statements, including the notes to the consolidated financial statements, and Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of this report.

	(In thousands, except per share data)				
	Year Ended June 30,				
	<u>2007</u>	<u>2006 (1)</u>	<u>2005 (1)</u>	<u>2004</u>	<u>2003</u>
<b>Statement of Operations Data:</b>					
<b>REVENUES</b>					
Licenses, grants and contracts (2)	\$ 14,406	\$ 18,240	\$ 13,897	\$ 2,315	\$ 1,270
Royalties	-	1,509	1,586	-	-
Product sales	-	-	2,474	-	-
Total revenues	14,406	19,749	17,957	2,315	1,270
<b>OPERATING EXPENSES</b>					
Cost of product sales	-	2,041	535	-	-
Royalties	-	300	328	-	-
Research and development	36,914	41,014	25,045	23,333	17,439
General and administrative	7,293	6,844	7,461	5,740	4,867
Total operating expenses	44,207	50,199	33,369	29,073	22,306
<b>OTHER INCOME (EXPENSE)</b>					
Investment income	1,324	856	488	222	248
Interest expense	(53)	(31)	(14)	(23)	(22)
Total other income, net	1,271	825	474	199	226
Loss before income taxes	(28,530)	(29,625)	(14,938)	(26,559)	(20,810)
Income tax benefit	778	666	580	241	245
<b>NET LOSS</b>	<b>(27,752)</b>	<b>(28,959)</b>	<b>(14,358)</b>	<b>(26,318)</b>	<b>(20,565)</b>
<b>DEEMED DIVIDEND</b>					
<b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>	<b>\$ (27,752)</b>	<b>\$ (28,959)</b>	<b>\$ (14,358)</b>	<b>\$ (26,318)</b>	<b>\$ (20,768)</b>
Basic and diluted net loss attributable to common stockholders per common share	\$ (0.36)	\$ (0.48)	\$ (0.27)	\$ (0.55)	\$ (0.73)
Weighted average common shares outstanding	76,204	60,357	53,861	47,688	28,362
<b>Balance Sheet Data (at period end):</b>					
Cash, cash equivalents and investments	\$ 33,771	\$ 30,664	\$ 18,106	\$ 20,412	\$ 18,383
Property and equipment, net	6,070	6,348	6,464	6,356	7,246
Working capital	25,823	19,742	13,772	15,485	14,742
Total assets	42,781	40,047	35,166	27,800	26,568
Long-term debt, net of current portion	275	230	19	30	76
Stockholders' equity	18,532	18,300	9,225	19,387	18,657

- (1) In the fiscal year ended June 30, 2005, we received FDA approval to market NeutroSpec for equivocal appendicitis. We suspended sales of NeutroSpec during the fiscal year ended June 30, 2006.
- (2) In September 2007, we received notice from King, effective December 2007, terminating our collaborative development agreement, under which we earned license revenue and cost reimbursement revenue related to our bromelanotide program.



Table of Contents

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

The following discussion and analysis should be read in conjunction with the consolidated financial statements and notes to the consolidated financial statements filed as part of this annual report on Form 10-K.

**Critical Accounting Policies.**

Our significant accounting policies are described in Note 2 to the consolidated financial statements included in this annual report on Form 10-K. 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. Estimated reimbursements for research and development activities and government grants 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 to jointly develop and commercialize bremelanotide. Deferred revenue related to the King agreement has been recognized as revenue over the estimated period of our performance during the initial development term of this agreement. Specific performance periods were not stated in the agreement and were estimated by management based on detailed development programs agreed upon by the parties. In September 2007, we received notice from King terminating the agreement in accordance with its terms effective December 5, 2007. Upon termination, we will solely own all rights to bremelanotide. In connection with the termination of the agreement, we expect to recognize in our fiscal year ending June 30, 2008 all remaining deferred up-front license fees received from King, together with associated deferred costs, which prior to termination were being recognized as revenues and costs over the estimated period of our performance under the agreement. As of June 30, 2007, deferred revenue and deferred costs, included in other current assets and other assets, amounted to \$7,064,996 and \$886,479, respectively.

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 may 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 grantee terminations and certain changes in

our share price. As a result, share-based compensation charges may vary significantly from period to period.

Table of Contents**Results of Operations**

*Year Ended June 30, 2007 Compared to the Year Ended June 30, 2006:*

**Licenses, grants and contracts** In the year ended June 30, 2007 ( fiscal 2007 ), we recognized \$14.4 million of revenue from licenses, grants and contracts compared to \$18.2 million for the year ended June 30, 2006 ( fiscal 2006 ). In fiscal 2007 and fiscal 2006, we recognized \$12.9 million and \$17.9 million of revenue, respectively, from our collaboration agreement with King related to bremelanotide, consisting of (i) \$10.1 million and \$14.8 million, respectively, of reimbursements for King s share of bremelanotide development expenses and (ii) \$2.8 million and \$3.1 million, respectively, of license fees, which represents the portion of deferred revenue recognized during the year from King s August 2004 up-front payment. The decrease in reimbursement revenue from King is related to decreased reimbursable bremelanotide costs during the year. Reimbursable bremelanotide costs were higher in fiscal 2006 due to the conduct of two significant Phase 2 clinical trials. Upon the termination of our collaboration agreement with King, we will no longer receive such reimbursement revenue. In fiscal 2007, we recognized less license revenue related to the King agreement as a result of increasing our estimated period of performance under the agreement. In connection with the termination of our collaboration agreement, we expect to recognize in the year ending June 30, 2008 ( fiscal 2008 ) the remainder of the deferred revenue related to King s up-front payment. In fiscal 2007, we recognized \$1.2 million of revenue related to our January 2007 license agreement with AstraZeneca. This amount consists of \$0.6 million of revenue related to our research services performed during the year and \$0.6 million of license revenue related to AstraZeneca s \$10.0 million up-front license fee received at the inception of the agreement. Revenue from reimbursements for Mallinckrodt s share of NeutroSpec development expenses amounted to \$0.3 million and \$0.3 million in fiscal 2007 and 2006, respectively. Future contract revenue from AstraZeneca and Mallinckrodt, in the form of reimbursement of shared development costs and 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 certain development milestones.

**Royalties** For fiscal 2007 and fiscal 2006, we recognized royalty revenues of \$0 and \$1.5 million, respectively, on Mallinckrodt s sales of NeutroSpec, pursuant to our collaboration agreement. We received FDA approval to market NeutroSpec in July 2004 and suspended sales in December 2005. We will not earn future royalty revenues from NeutroSpec unless and until NeutroSpec sales resume.

**Cost of product sales and royalties** Royalty expense amounted to \$0 and \$0.3 million in fiscal 2007 and 2006, respectively. We will not incur future royalty expenses on NeutroSpec unless and until commercial sales of NeutroSpec resume.

**Research and development** Research and development ( R&D ) expenses decreased to \$36.9 million for fiscal 2007 compared to \$41.0 million for fiscal 2006. In fiscal 2007, development spending directly associated with bremelanotide decreased approximately \$5.9 million, from \$24.2 million in fiscal 2006 to \$18.3 million in fiscal 2007. Costs related to the conduct of various clinical trials were higher in fiscal 2006, including costs of an at-home efficacy study in ED patients and an at-home efficacy study in ED patients with diabetes mellitus. Associated costs include fees to clinicians, laboratory expenses and study monitoring and management. Partially offsetting decreased clinical study costs were greater process development and manufacturing costs in fiscal 2007. In fiscal 2007, fiscal 2006 and the year ended June 30, 2005 ( fiscal 2005 ) and cumulatively to date, we have incurred approximately \$27.5 million, \$33.2 million, \$18.3 million and \$111.6 million, respectively, in R&D expenses on bremelanotide, including an allocated portion of general R&D expenses. Spending to date has been primarily related to formulation, manufacturing, preclinical and clinical activities. Bremelanotide spending in fiscal 2008 will be dependent on our review of the FDA s comments and decisions regarding the design and timing of any future clinical trials.

Research and development expenses directly related to our obesity, CHF and other preclinical programs increased from \$2.6 million in fiscal 2006 to \$3.8 million in fiscal 2007. Spending on our obesity and CHF programs increased approximately \$0.4 million and \$0.8 million, respectively. In fiscal 2007, fiscal 2006 and fiscal 2005 and cumulatively to date, we have incurred approximately \$9.0 million, \$5.1 million, \$3.7 million and \$32.1 million, respectively, in R&D expenses on these preclinical programs, including an allocated portion of general R&D expenses. Spending to date has been primarily related to the identification and optimization of lead compounds. We expect to spend approximately \$2 million to \$3 million of direct costs during fiscal 2008 on laboratory research on various compounds, which may increase in the event we file an IND and commence clinical trials for a compound. The amount of such spending and the nature of future development activities are dependent on a number of factors, including primarily the success of our discovery programs, preclinical studies, our ability to progress a compound into human clinical trials and discussions with AstraZeneca and other potential development partners.

Table of Contents

In fiscal 2007, research and development spending directly related to NeutroSpec decreased to \$0.4 million from \$1.1 million in fiscal 2006, primarily as a result of lower costs related to manufacturing and process development activities. We have suspended substantial development activities, including research to evaluate NeutroSpec's potential as an imaging agent for other indications such as osteomyelitis (infection deep inside a bone), fever of unknown origin, post surgical infection, inflammatory bowel disease and pulmonary imaging. We expect to spend approximately \$0.1 million to \$0.3 million of direct costs on NeutroSpec on a quarterly basis in this calendar year to review the safety of NeutroSpec and explore other indications, a portion of which will be reimbursed by our collaboration partner, Mallinckrodt. The amount of such spending and the nature of future development activities are dependent on a number of factors, including primarily the review of NeutroSpec safety and discussions with both the FDA and Mallinckrodt. In fiscal 2007, fiscal 2006 and fiscal 2005 and cumulatively to date, we have incurred approximately \$0.4 million, \$2.7 million, \$3.1 million and \$55.0 million, respectively, in R&D expenses on NeutroSpec, including an allocated portion of general R&D expenses. Spending to date has been primarily related to an initial indication of imaging equivocal appendicitis.

Total general R&D expenses, increased from \$12.9 million in fiscal 2006 to \$14.5 million in fiscal 2007, primarily due to increased personnel costs, including higher costs for stock-based compensation, and additions to laboratory facilities.

*General and administrative* General and administrative expenses increased from \$6.8 million in fiscal 2006 to \$7.3 million in fiscal 2007. The increase primarily reflects higher personnel costs in fiscal 2007, including higher stock-based compensation expense. Increased legal expenses related to collaborative agreements and arbitration proceedings partially offset lower insurance costs that followed the withdrawal of NeutroSpec.

*Investment income* Investment income increased to \$1.3 million for fiscal 2007 from \$0.9 million for fiscal 2006, primarily reflecting income on greater invested cash balances maintained during the period as a result of our February 2007 registered direct offering of common stock and the initial license fee from AstraZeneca.

*Income tax benefit* During fiscal 2007 and fiscal 2006, we sold New Jersey state net operating loss carryforwards, which resulted in the recognition of \$0.8 million and \$0.7 million of income tax benefits, respectively. Assuming the state of New Jersey continues to fund this program, which is not assured, the amount of net operating losses and tax credits we may sell will depend upon the allocation among qualifying companies of an annual pool established by the state of New Jersey.

*Year Ended June 30, 2006 Compared to the Year Ended June 30, 2005:*

*Licenses, grants and contracts* For fiscal 2006, we recognized \$18.2 million of revenue from licenses, grants and contracts compared to \$13.9 million for fiscal 2005. In fiscal 2006 and fiscal 2005, we recognized \$17.9 million and \$11.5 million of revenue, respectively, related to our collaboration agreement with King related to bremelanotide, consisting of (i) \$14.8 million and \$8.1 million, respectively, of reimbursements for King's share of bremelanotide development expenses and (ii) \$3.1 million and \$3.4 million, respectively, of license fees, which represents the portion of King's August 2004 up-front payment recognized as revenue during the year. The increase in reimbursement revenue from King is related to increased bremelanotide costs during the year and to the existence of the collaboration agreement for the full fiscal year. The agreement with King was completed in August 2004. In fiscal 2006 and fiscal 2005, we recognized \$0.3 million and \$2.3 million of revenue, respectively, related to our collaboration agreement with Mallinckrodt related to NeutroSpec, consisting of (i) \$0.3 million and \$0.3 million, respectively, of reimbursements for Mallinckrodt's share of NeutroSpec development expenses and (ii) \$0 and \$2.0 million, respectively, of license fees. In fiscal 2005, we earned a \$2.0 million milestone payment from Mallinckrodt upon FDA approval of NeutroSpec.

*Royalties* For fiscal 2006 and fiscal 2005, we recognized royalty revenues of \$1.5 million and \$1.6 million, respectively, on Mallinckrodt's sales of NeutroSpec, pursuant to our collaboration agreement. Royalty revenues were comparable in fiscal 2006 and fiscal 2005, reflecting higher unit sales by Mallinckrodt during the shorter, six-month period of fiscal 2006 in which the product was sold.

*Product sales* Prior to the suspension of sales and marketing activities, we earned revenue from product sales on our shipment of manufactured units of NeutroSpec to Mallinckrodt, which were billed upon shipment of product to Mallinckrodt on standard trade terms. Revenue was recognized upon acceptance of the product by Mallinckrodt based on conformance with product specifications. Each Mallinckrodt purchase of NeutroSpec from us was subject to certain minimum quantities, resulting in a limited number of product shipments. Accordingly, our periodic revenue from product sales was highly dependent on the timing of orders and shipments. There were no sales of NeutroSpec to Mallinckrodt during fiscal 2006.

Table of Contents

*Cost of product sales and royalties* As noted above, there were no sales of NeutroSpec to Mallinckrodt in fiscal 2006. In fiscal 2006, cost of product sales represents our write-off of inventory due to the suspension of sales of NeutroSpec. For fiscal 2005, we recognized \$0.5 million in cost of product sales related to shipments of NeutroSpec to Mallinckrodt. Prior to the FDA approval of NeutroSpec in July 2004, all costs associated with the manufacturing of NeutroSpec were included in research and development expenses when incurred, including costs of usable raw materials and finished goods in inventory at the date of approval. As we used and sold this inventory, the cost of product sales we recognized excluded amounts previously expensed. On the date of approval, we had sufficient active drug substance to produce all of the product units sold prior to December 2005. Cost of sales for these units primarily consisted of packaging and other materials.

Royalty expense amounted to approximately \$0.3 million in each of fiscal 2006 and fiscal 2005. We will not incur future royalty expenses on NeutroSpec unless and until commercial sales of NeutroSpec resume.

*Research and development* Research and development expenses increased to \$41.0 million for fiscal 2006 compared to \$25.0 million for fiscal 2005. In fiscal 2006, development spending directly associated with bremelanotide increased approximately \$11.2 million, as increased clinical study costs related to the conduct of various clinical trials, including an at-home efficacy study in ED patients and an at-home efficacy study in ED patients with diabetes mellitus were partially offset by lower formulation development costs. Associated costs include fees to clinicians, laboratory expenses and study monitoring and management.

Research and development expenses directly related to our obesity, CHF and other preclinical programs increased from \$1.3 million to \$2.6 million from fiscal 2005 to fiscal 2006, primarily as a result of additional contract services for assistance with the optimization of lead compounds.

In fiscal 2006, research and development spending directly related to NeutroSpec decreased slightly from \$1.3 million in fiscal 2005 to \$1.1 million, primarily as a result of lower costs related to clinical trials.

Total general R&D expenses increased \$3.6 million in fiscal 2006, primarily due to increased personnel costs, including the recognition of compensation costs for stock option grants, the expansion of facilities and associated support costs.

*General and administrative* General and administrative expenses decreased from \$7.5 million in fiscal 2005 to \$6.8 million in fiscal 2006. Increased personnel costs in fiscal 2006 were more than offset by lower legal and consulting expenses. Legal expenses related to collaborative agreements and arbitration proceedings, recruiting fees and expenses related to compliance with new regulatory requirements were all higher in fiscal 2005.

*Investment income* Investment income increased to \$0.9 million for fiscal 2006 from \$0.5 million for fiscal 2005, primarily reflecting higher cash balances resulting from our sales of common stock and warrants.

*Income tax benefit* During fiscal 2006 and fiscal 2005, we sold New Jersey state net operating loss carryforwards, which resulted in the recognition of \$0.7 million and \$0.6 million of income tax benefits, respectively.

**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 revenue received under collaborative agreements.

We will need regulatory approval to market and sell our products. 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; and

marketing, sales and competition.

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

### Table of Contents

Failure to obtain timely regulatory approval for our other 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.

During fiscal 2007, we used \$22.1 million of cash for our operating activities, compared to \$23.4 million in fiscal 2006 and \$5.1 million in fiscal 2005. In fiscal 2007, the receipt of \$10.0 million in license fees from AstraZeneca offset higher cash outflows for operating expenses and the effect of higher reimbursement receipts from King in fiscal 2006. Lower net cash outflows from operations in fiscal 2005 resulted from lower operating expenses, amounts received from King under our collaboration agreement, which was completed in August 2004 and sales and royalties related to NeutroSpec. Our periodic accounts receivable balances will continue to be highly dependent on the timing of receipts from our development partners. Upon the termination of our collaboration agreement with King, we will no longer receive reimbursement revenue from them.

In fiscal 2007, net cash provided by financing activities was \$26.0 million primarily reflecting proceeds from the sale of common stock in a registered direct offering completed 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. Net cash provided by financing activities in fiscal 2005 of \$3.8 million resulted primarily from the issuance of common stock and warrants to King in connection with the August 2004 collaboration agreement.

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. We believe that our cash, cash equivalents and available-for-sale investments as of June 30, 2007, together with expected receipts from collaboration and license agreements and other income, are adequate to fund our operations for at least the next twelve months. 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.

We are actively searching for certain products and technologies to license or acquire, now or in the future, and expect to continue to do so. 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 such an acquisition is identified.

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 pre-clinical studies and clinical trials, obtain required regulatory approvals and successfully manufacture, market and sell 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, 2007:

	Total	Payments due by Period			After 5 Years
		Less than 1 Year	1 - 3 Years	3 - 5 Years	
Facility operating leases	\$ 9,435,945	\$ 2,572,281	\$ 3,026,081	\$ 3,081,697	\$ 755,886
Capital lease obligations	454,075	176,418	238,694	38,963	-
Notes payable	100,708	67,139	33,569	-	-
License agreements	1,225,000	175,000	350,000	350,000	350,000
Total contractual obligations	\$ 11,215,728	\$ 2,990,838	\$ 3,648,344	\$ 3,470,660	\$ 1,105,886





Table of Contents

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 reasonably expect to make any such contingent payments during the next twelve months.

We have a license agreement for patent rights related to certain compounds and methods of treatment for sexual dysfunction. The license agreement requires contingent payments based on certain upfront fees we receive as a result of a sublicense. We do not reasonably expect to sublicense such rights or make any material contingent payments during the next twelve months.

**Item 7A. Quantitative and Qualitative Disclosures about Market Risk.**

*Interest Rate Risk.* Our exposure to market risk from changes in interest rates relates primarily to our investment portfolio. As of June 30, 2007, our cash and cash equivalents were \$31.4 million and investments, which consisted of mutual funds, were \$2.3 million. As of June 30, 2006, our cash and cash equivalents were \$28.3 million and investments, which consisted of mutual funds, were \$2.3 million. Due to the average maturity and conservative nature of our investment portfolio, we do not believe that short term fluctuations in interest rates would materially affect the value of our securities.

*Foreign Currency Risk.* Certain of our operating expenses are billed to us and settled in foreign currencies, primarily the Euro. As of June 30, 2007 and 2006, the amount of accounts payable and accrued expenses denominated in Euros was approximately \$0.2 million. Percentage increases in the U.S. dollar cost of Euros would result in corresponding increases in such liabilities. We have not hedged our exposures to foreign exchange fluctuations. However, we monitor our foreign-currency denominated liabilities and commitments on an ongoing basis and may enter into hedging transactions in the future.

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 Report:

	<b><u>Page</u></b>
<u>Report of Independent Registered Public Accounting Firm</u>	28
<u>Consolidated Balance Sheets</u>	29
<u>Consolidated Statements of Operations</u>	30
<u>Consolidated Statements of Cash Flows</u>	31
<u>Consolidated Statements of Stockholders' Equity</u>	32
<u>Notes to Consolidated Financial Statements</u>	33

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 as of June 30, 2007 and 2006, 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, 2007. 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, 2007 and 2006, and the results of their operations and their cash flows for each of the years in the three-year period ended June 30, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 2, the Company adopted SFAS No. 123(R), Share-Based Payment, effective July 1, 2005 using the modified prospective method.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Palatin Technologies, Inc.'s internal control over financial reporting as of June 30, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated September 12, 2007 expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

/s/ KPMG LLP

Philadelphia, Pennsylvania  
September 12, 2007

Table of Contents (Financial)**PALATIN TECHNOLOGIES, INC.****Consolidated Balance Sheets**

	<b>June 30, 2007</b>	<b>June 30, 2006</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 31,447,615	\$ 28,333,211
Available-for-sale investments	2,323,642	2,330,834
Accounts receivable	607,841	69,591
Prepaid expenses and other current assets	1,008,464	1,453,650
Total current assets	35,387,562	32,187,286
Property and equipment, net	6,070,226	6,347,705
Restricted cash	475,000	475,000
Other assets	848,446	1,037,296
Total assets	\$ 42,781,234	\$ 40,047,287
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Capital lease obligations and notes payable, current portion	\$ 216,841	\$ 86,564
Accounts payable	1,120,894	3,092,962
Accrued expenses	2,420,837	4,466,428
Accrued compensation	941,300	803,900
Deferred revenue, current portion	4,864,833	3,995,575
Total current liabilities	9,564,705	12,445,429
Capital lease obligations and notes payable, net of current portion	275,126	229,585
Deferred rent, net of current portion	1,966,628	2,358,550
Deferred revenue, net of current portion	12,443,087	6,713,942
Total liabilities	24,249,546	21,747,506
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock of \$.01 par value authorized 10,000,000 shares; Series A Convertible; issued and outstanding 4,997 and 9,997 shares as of June 30, 2007 and 2006, respectively	50	100
Common stock of \$.01 par value authorized 150,000,000 shares; issued and outstanding 85,126,915 and 70,878,521 shares as of June 30, 2007 and 2006, respectively	851,269	708,785
Additional paid-in capital	205,875,438	178,089,176
Accumulated other comprehensive loss	-	(54,736)
Accumulated deficit	(188,195,069)	(160,443,544)
Total stockholders' equity	18,531,688	18,299,781
Total liabilities and stockholders' equity	\$ 42,781,234	\$ 40,047,287

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

Table of Contents (Financial)

## PALATIN TECHNOLOGIES, INC.

## Consolidated Statements of Operations

	<b>Year Ended June 30,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
<b>REVENUES:</b>			
Licenses, grants and contracts	\$ 14,405,665	\$ 18,239,783	\$ 13,896,818
Royalties	-	1,508,862	1,586,050
Product sales	-	-	2,474,325
Total revenues	14,405,665	19,748,645	17,957,193
<b>OPERATING EXPENSES:</b>			
Cost of product sales	-	2,041,175	534,932
Royalties	-	299,995	328,401
Research and development	36,913,739	41,013,894	25,045,279
General and administrative	7,293,090	6,843,817	7,460,607
Total operating expenses	44,206,829	50,198,881	33,369,219
Loss from operations	(29,801,164)	(30,450,236)	(15,412,026)
<b>OTHER INCOME (EXPENSE):</b>			
Investment income	1,324,671	855,601	488,262
Interest expense	(53,339)	(30,522)	(14,487)
Total other income, net	1,271,332	825,079	473,775
Loss before income taxes	(28,529,832)	(29,625,157)	(14,938,251)
Income tax benefit	778,308	666,275	580,275
<b>NET LOSS</b>	<b>\$(27,751,524)</b>	<b>\$(28,958,882)</b>	<b>\$(14,357,976)</b>
Basic and diluted net loss per common share	\$ (0.36)	\$ (0.48)	\$ (0.27)
Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share	76,204,160	60,356,610	53,861,182

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

Table of Contents (Financial)

## PALATIN TECHNOLOGIES, INC.

## Consolidated Statements of Cash Flows

	<b>Year Ended June 30,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (27,751,525)	\$ (28,958,882)	\$ (14,357,976)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,449,577	1,263,899	1,075,306
Realized loss on investments	61,928	-	114,551
Stock-based compensation	1,726,825	1,167,177	983
Changes in certain operating assets and liabilities:			
Accounts receivable	(538,250)	5,371,834	(5,441,425)
Inventories	-	1,382,160	(1,382,160)
Prepaid expenses and other	673,991	805,368	(2,422,621)
Accounts payable	(1,972,068)	(1,680,335)	2,753,327
Accrued expenses and other	(2,300,113)	155,622	1,174,199
Deferred revenues	6,598,403	(2,954,749)	13,422,266
Net cash used in operating activities	(22,051,232)	(23,447,906)	(5,063,550)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Maturity of investments	-	-	50,000
Purchases of property and equipment	(862,471)	(819,953)	(968,001)
Net cash used in investing activities	(862,471)	(819,953)	(918,001)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Payments on capital lease obligations and notes payable	(173,764)	(40,268)	(33,491)
Proceeds from common stock, stock option and warrant issuances, net	26,201,871	36,920,974	3,788,330
Net cash provided by financing activities	26,028,107	36,880,706	3,754,839
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>3,114,404</b>	<b>12,612,847</b>	<b>(2,226,712)</b>
<b>CASH AND CASH EQUIVALENTS, beginning of year</b>	<b>28,333,211</b>	<b>15,720,364</b>	<b>17,947,076</b>
<b>CASH AND CASH EQUIVALENTS, end of year</b>	<b>\$ 31,447,615</b>	<b>\$ 28,333,211</b>	<b>\$ 15,720,364</b>
<b>SUPPLEMENTAL CASH FLOW INFORMATION:</b>			
Cash paid for interest	\$ 53,339	\$ 30,522	\$ 14,171
Equipment acquired under financing arrangements	316,862	326,214	-
Tenant allowances recognized in deferred rent	-	-	210,924
Common stock issued for license fees	-	-	317,900

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



Table of Contents (Financial)

## PALATIN TECHNOLOGIES, INC.

## Consolidated Statements of Stockholders' Equity

	Preferred Stock		Common Stock		Additional Paid-in	Deferred Compensation	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Capital	Compensation	Loss	Deficit	
Balance, July 1, 2004	11,697	\$ 117	52,790,589	\$ 527,906	\$ 136,148,482	\$(78,407)	\$(84,772)	\$(117,126,686)	\$ 19,386,640
Sale of common shares, net of costs	-	-	1,176,125	11,761	3,566,684	-	-	-	3,578,445
Issuance of common shares for license fees	-	-	170,000	1,700	316,200	-	-	-	317,900
Conversion of preferred shares	(250)	(3)	9,505	95	(92)	-	-	-	-
Exercise of options and warrants	-	-	90,325	903	208,982	-	-	-	209,885
Stock-based compensation	-	-	-	-	(72,825)	-	-	-	(72,825)
Amortization of deferred compensation	-	-	-	-	-	78,407	-	-	78,407
Comprehensive loss:									
Unrealized loss on investments	-	-	-	-	-	-	(29,779)	-	(29,779)
Reclassification adjustment for realized losses included in net loss							114,551		114,551
Net loss	-	-	-	-	-	-	-	(14,357,976)	(14,357,976)
Total comprehensive loss									(14,273,204)
Balance, June 30, 2005	11,447	114	54,236,544	542,365	140,167,431	-	-	(131,484,662)	9,225,248
Sale of common shares, net of costs	-	-	15,478,013	154,780	34,669,275	-	-	-	34,824,055
Conversion of preferred shares	(1,450)	(14)	55,723	557	(543)	-	-	-	-
Exercise of options and warrants	-	-	1,108,241	11,083	2,085,836	-	-	-	2,096,919
Stock-based compensation	-	-	-	-	1,167,177	-	-	-	1,167,177

Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

Comprehensive loss:									
Unrealized loss on investments	-	-	-	-	-	-	(54,736)	-	(54,736)
Net loss	-	-	-	-	-	-	-	(28,958,882)	(28,958,882)
Total comprehensive loss									(29,013,618)
Balance, June 30, 2006	9,997	100	70,878,521	708,785	178,089,176	-	(54,736)	(160,443,544)	18,299,781
Sale of common shares, net of costs	-	-	13,750,000	137,500	25,372,402	-	-	-	25,509,902
Conversion of preferred shares	(5,000)	(50)	199,203	1,992	(1,942)	-	-	-	-
Exercise of options and warrants	-	-	299,191	2,992	688,976	-	-	-	691,969
Stock-based compensation	-	-	-	-	1,726,825	-	-	-	1,726,825
Comprehensive loss:									
Unrealized loss on investments	-	-	-	-	-	-	(7,192)	-	(7,192)
Reclassification adjustment for realized losses included in net loss								61,928	61,928
Net loss	-	-	-	-	-	-	-	(27,751,525)	(27,751,525)
Total comprehensive loss									(27,696,789)
Balance, June 30, 2007	4,997	\$ 50	85,126,915	\$851,269	\$205,875,438	\$	-	\$(188,195,069)	\$ 18,531,688

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

Table of Contents (Financial)

**PALATIN TECHNOLOGIES, INC.**  
**Notes to Consolidated Financial Statements**

**(1) ORGANIZATION:**

*Nature of Business* Palatin Technologies, Inc. ( Palatin or the Company ) is a biopharmaceutical company primarily focused on discovering and developing targeted, receptor-specific small molecule and peptide therapeutics, including melanocortin ( MC )-based therapeutics. Therapeutics affecting the activity of the MC family of receptors may have the potential to treat a variety of conditions and diseases, including sexual dysfunction, obesity and related disorders, cachexia (extreme wasting, generally secondary to a chronic disease), skin pigmentation disorders and inflammation-related diseases. The Company is exploring other receptor-specific therapeutics, including congestive heart failure therapeutics.

Bremelanotide, an MC receptor agonist, is a patented, nasally-administered peptide in clinical development for the treatment of both male and female sexual dysfunction. In August 2004, the Company entered into a collaborative development and marketing agreement with King Pharmaceuticals, Inc. ( King ) for bremelanotide. See Note 11 regarding subsequent events pertaining to the agreement with King.

The Company has a licensing and research collaboration agreement with AstraZenecaAB ( AstraZeneca ) to discover, develop and commercialize small molecule compounds that target MC receptors for the treatment of obesity, diabetes and related metabolic syndrome. The Company is also conducting research on peptidomimetic compounds for the treatment of other disorders, including congestive heart failure. Certain compounds under investigation result from the Company's MIDAS(TM) technology, a proprietary platform technology to design and synthesize compounds that mimic the activity of peptides.

NeuroSpec is the Company's radiolabeled monoclonal antibody product for imaging and diagnosing infection and the subject of a strategic collaboration agreement with the Mallinckrodt division of Covidien ( Mallinckrodt ). In July 2004, the Company received approval from the U.S. Food and Drug Administration to market NeuroSpec for imaging and diagnosing equivocal appendicitis. In December 2005, the Company and Mallinckrodt voluntarily suspended the sales, marketing and distribution of NeuroSpec following the occurrence of certain serious adverse events involving patients who received NeuroSpec. Significant development activities pertaining to NeuroSpec are currently suspended while the Company and Mallinckrodt evaluate future development and marketing alternatives.

Key elements of the Company's business strategy include entering into alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of the Company's product candidates under development, expansion of the Company's pipeline through the utilization of its MC expertise and patented drug discovery platform, opportunistic acquisition of synergistic products and technologies and partial funding of the Company's development and discovery programs with the cash flow from collaboration agreements.

*Business Risk and Liquidity* The Company has incurred negative cash flows from operations since its inception, and has expended, and expects to continue to expend in the future, substantial funds to complete its planned product development efforts. As shown in the accompanying consolidated financial statements, the Company has an accumulated deficit as of June 30, 2007 and incurred a net loss for the fiscal year ended June 30, 2007. The Company anticipates incurring additional losses in the future as a result of spending on its development programs. To achieve profitability, the Company, alone or with others, must successfully develop and commercialize its technologies and proposed products, conduct successful pre-clinical studies and clinical trials, obtain required regulatory approvals and successfully manufacture and market such technologies and proposed products. The time required to reach profitability is highly uncertain, and there can be no assurance that the Company will be able to achieve profitability on a sustained basis, if at all.

The Company believes that its cash, cash equivalents and available-for-sale investments as of June 30, 2007, together with expected receipts from collaboration and license agreements and other income, are

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

### Table of Contents (Financial)

adequate to fund operations for at least the next twelve months. The nature and timing of the Company's development activities are highly dependent on its financing activities. Management plans to continue to refine its operations, control expenses, evaluate alternative methods to conduct its business, and seek available and attractive sources of financing and sharing of development costs through strategic collaboration agreements or other resources. Should appropriate sources of financing not be available, management would delay certain clinical trials and research activities until such time as appropriate financing was available. There can be no assurance that the Company's financing efforts will be successful. If adequate funds are not available, the Company's financial condition will be materially and adversely affected, due to the Company's expected negative cash flows from operations.

**Concentrations** Concentrations in the Company's assets and operations subject it to certain related risks. Financial instruments that subject the Company to concentrations of credit risk primarily consist of cash and cash equivalents, available-for-sale investments and accounts receivable. The Company's cash and cash equivalents are primarily invested in one money market fund sponsored by a large financial institution. The Company's accounts receivable balance as of June 30, 2007 consists primarily of amounts due from AstraZeneca.

Revenues from collaboration partners as a percentage of total revenues were as follows (see Note 11 regarding subsequent events):

	<b>Year Ended June 30,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
King	90%	91%	64%
AstraZeneca	9%	-%	-%
Mallinckrodt	1%	9%	36%

### **(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:**

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

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

**Cash and Statements of Cash Flows** Cash and cash equivalents include cash on hand, cash in banks and all highly liquid investments with a purchased maturity of less than three months. Restricted cash secures letters of credit for security deposits on leases.

**Investments** The Company classifies its investments as available-for-sale investments and all such investments are recorded at fair value based on quoted market prices. Unrealized holding gains and losses, net of the related tax effect, if any, are generally excluded from earnings and are reported in accumulated other comprehensive loss until realized. Interest and dividends on securities classified as available-for-sale are included in investment income. Gains and losses are recorded in the statement of operations when realized or when unrealized holding losses are determined to be other than temporary, on a specific-identification basis.

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

**Inventories** The Company's inventories of NeutroSpec were valued at the lower of cost or market using the first-in, first-out method and excluded certain costs incurred prior to the FDA approval of NeutroSpec in July 2004, which were charged directly to research and development expense. Inventory costs consisted primarily of costs to third-party vendors for work-in-progress materials and did not include

Table of Contents (Financial)

general and administrative costs. In the year ended June 30, 2006, the Company wrote off existing inventories of NeutroSpec upon suspension of sales and marketing activities with a charge of \$2,041,175 to cost of product sales.

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

*Impairment of Long-Lived Assets* The Company reviews its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. To determine recoverability of a long-lived asset, management evaluates whether the estimated future undiscounted net cash flows from the asset, without interest charges, are less than its carrying amount. If impairment is indicated, the long-lived asset would be written down to fair value. Fair value is determined by an evaluation of available price information at which assets could be bought or sold, including quoted market prices, if available, or the present value of the estimated future cash flows based on reasonable and supportable assumptions.

*Other Assets* Other assets and other current assets include certain payments the Company made to licensors in cash and stock as their share of up-front payments received from collaboration partners in connection with the Company's collaboration agreements. The Company has treated these payments as incremental direct costs of the up-front payments, to be charged over the same period as the related deferred revenue is recognized, in accordance with guidance contained in the SEC's Staff Accounting Bulletin No. 104, Revenue Recognition and, by analogy, to paragraph 4 of Financial Accounting Standards Board (FASB) Technical Bulletin 90-1, Accounting for Separately Priced Extended Warranty and Product Maintenance Contracts. See Note 11 regarding subsequent events.

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

*Revenue Recognition* Revenue from corporate collaborations and licensing agreements consists of up-front fees, research and development funding, and milestone payments. Non-refundable up-front fees are deferred and amortized to revenue on a straight-line basis over the related performance period. The Company estimates the performance period as the period in which it performs certain development activities under the applicable agreement. Estimated reimbursements for research and development activities and government grants are recorded in the period that the Company performs the related activities under the terms of the applicable agreements. Revenue resulting from the achievement of milestone events stipulated in the applicable agreements is recognized when the milestone is achieved, provided that such milestone is substantive in nature.

Royalty revenues represent amounts due from Mallinckrodt and were earned based on a contractual percentage of Mallinckrodt's net sales of NeutroSpec to customers. Revenue was recognized by the Company in the period in which Mallinckrodt's net sales occurred, as reported by Mallinckrodt to the Company on a quarterly basis.

Product sales represent the sale of NeutroSpec by the Company to Mallinckrodt, pursuant to the collaboration agreement. Product sales were billed upon shipment of product to Mallinckrodt. Revenue was recognized upon acceptance of the product by Mallinckrodt based on conformance with product specifications. Upon acceptance of the product, Mallinckrodt did not have the right of return or right to cancel or terminate the sale.

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

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

### Table of Contents (Financial)

*Stock Options* Effective July 1, 2005, the Company adopted Statement of Financial Accounting Standards ( SFAS ) 123(R), Share-Based Payment, using the modified prospective method. SFAS 123(R) establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services and requires that the compensation cost relating to share-based payment transactions be recognized in financial statements, measured by the fair value of the equity or liability instruments issued, adjusted for estimated forfeitures.

Prior to the adoption of SFAS 123(R), the Company applied the intrinsic-value-based method of accounting prescribed by Accounting Principles Board Opinion ( APB ) 25, Accounting for Stock Issued to Employees, and related interpretations, to account for its fixed-plan stock options to employees. Under this method, compensation cost was recorded only if the market price of the underlying stock on the date of grant exceeded the exercise price. SFAS 123, Accounting for Stock-Based Compensation, established accounting and disclosure requirements using a fair-value-based method of accounting for stock-based employee compensation plans. As permitted by SFAS 123, the Company elected to continue to apply the intrinsic-value-based method of accounting described above, and adopted only the disclosure requirements of SFAS 123. The fair-value-based method used to determine historical pro forma amounts under SFAS 123 was similar in most respects to the method used to determine stock-based compensation expense under SFAS 123(R). However, in its pro forma disclosures below, the Company accounted for option forfeitures as they occurred, rather than based on estimates of future forfeitures.

The pro forma impact on the Company's net loss using the fair-value-based method of accounting for stock-based compensation under SFAS 123 for the year ended June 30, 2005 is as follows:

Net loss:	
As reported	\$(14,357,976)
Stock-based employee compensation expense included in the determination of net loss as reported	(15,879)
Impact of total stock-based compensation expense determined under fair-value-based method	(1,067,519)
Pro forma	\$(15,441,374)
Basic and diluted net loss per common share:	
As reported	\$ (0.27)
Pro forma	\$ (0.29)

#### Weighted average valuation assumptions:

Expected life of options in years	7
Risk-free interest rate	3.9%
Expected volatility	87%
Expected dividend yield	0%

The Company accounts for options granted to consultants in accordance with Emerging Issues Task Force ( EITF ) Issue 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. The Company determines the value of stock options utilizing the Black-Scholes option-pricing model.

Compensation costs for fixed awards with pro rata vesting are allocated to periods on the straight-line basis.

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

Table of Contents (Financial)

In accordance with SFAS 109, Accounting for Income Taxes, the Company has recorded a valuation allowance against its deferred tax assets. The valuation allowance is based on management's estimates and analysis, which includes provisions of tax laws that may limit the Company's ability to utilize its net operating loss carryforwards.

During the years ended June 30, 2007, 2006 and 2005, the Company sold New Jersey state net operating loss carryforwards and research and development credit carryforwards, which resulted in the recognition of tax benefits.

*Net Loss per Common Share* Basic earnings per share (EPS) is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted EPS reflects the potential dilution from the exercise or conversion of securities into common stock, including stock options and warrants, restricted stock units and shares of Series A Convertible Preferred Stock. For the years ended June 30, 2007, 2006 and 2005, there were no dilutive effects of such securities as the Company incurred a net loss in each period. Common shares issuable upon conversion of Series A Convertible Preferred Stock, the exercise of outstanding options and warrants and the vesting of restricted stock units amounted to an aggregate of 16,512,769, 15,954,843, and 13,384,915 as of June 30, 2007, 2006 and 2005, respectively.

*New Accounting Pronouncements* The FASB has issued SFAS 157, Fair Value Measurements, which addresses how companies should measure fair value for recognition or disclosure purposes, and SFAS 159, The Fair Value Option for Financial Assets and Financial Liabilities, which permits companies to measure certain financial instruments and other items at fair value. The Company will be required to adopt these standards beginning with its fiscal year ending June 30, 2008. The impact of adopting these standards on the Company's consolidated financial statements is not known.

**(3) AGREEMENT WITH KING**

In August 2004, the Company entered into a Collaborative Development and Marketing Agreement with King to jointly develop and commercialize bremelanotide. Pursuant to the terms of the agreement, King and Palatin share collaboration development and marketing costs and collaboration net profits derived from net sales of bremelanotide in North America based on an agreed percentage.

King paid the Company \$20,000,000 at the closing of the agreement in August 2004 and purchased Company common stock and warrants for an aggregate of \$10,000,000 in September 2005, as described in Note 9.

Of the \$20,000,000 payment received at closing, \$3,606,672 was recorded as equity, based on the estimated fair value of 1,176,125 shares of common stock and three-year warrants to purchase 235,225 shares of common stock at \$4.25 per share which were issued to King, and \$16,393,328 was recorded as deferred revenue related to licenses granted to King and services to be performed by the Company. The Company has determined that the licenses and services should be evaluated together as a single unit of accounting for the purposes of revenue recognition based on guidance in EITF Issue 00-21, Revenue Arrangements with Multiple Deliverables. Accordingly, the deferred revenue is being recognized as revenue over the period of the Company's performance during the initial development term of this agreement, which, as of June 30, 2007, was estimated to be approximately six years from the inception of the agreement. Specific performance periods are not stated in the agreement and have been estimated by management based on detailed development programs agreed upon by the parties. Management monitors the progress and results of these development activities and adjusts the estimated performance period accordingly. Increases in the estimated performance period result in increases in the period over which such deferred revenue is to be recognized and corresponding decreases in the amount of revenue recognized each period. For the years ended June 30, 2007, 2006 and 2005, the Company recognized as revenue \$2,808,441, \$3,159,496 and \$3,360,394, respectively, of the deferred revenue.

See Note 11 regarding subsequent events.

**(4) AGREEMENT WITH ASTRAZENECA**

In January 2007, the Company entered into an exclusive global licensing and research collaboration agreement with AstraZeneca to discover, develop and commercialize small molecule compounds that target MC receptors for the treatment of obesity, diabetes and related metabolic syndrome.

Table of Contents (Financial)

The collaboration is based on the Company's MC receptor obesity program and includes access to compound libraries, core technologies and expertise in MC receptor drug discovery and development.

Under the terms of the agreement, the Company received an up-front payment of \$10,000,000 from AstraZeneca and is eligible for milestone payments totaling \$300,000,000, with up to \$180,000,000 contingent upon development and regulatory milestones and the balance contingent on achievement of sales targets. In addition, the Company would receive royalties on sales of any approved products. AstraZeneca assumed responsibility for product commercialization, product discovery and development costs, with both companies contributing scientific expertise in the research collaboration. In addition, the Company is providing research services to AstraZeneca at a contractual rate per full-time-equivalent employee.

The Company has determined that the license agreement and research services should be evaluated together as a single unit for the purposes of revenue recognition pursuant to EITF Issue 00-21. Accordingly, the up-front payment of \$10,000,000 received by the Company as a license fee is being recognized as revenue on a straight-line basis over the maximum period during which the Company may perform research services under the agreement. Per-employee compensation from AstraZeneca for research services is recognized as earned at the contractual rate, which approximates the fair value of such services. Payments received upon the attainment of substantive milestones are recognized as revenue when earned. If the Company's estimated period of performance is reduced to less than the maximum, the amortization period for any remaining deferred revenue will also be reduced. For the year ended June 30, 2007, the Company recognized as revenue \$694,444 of the deferred revenue.

**(5) INVESTMENTS**

The following is a summary of available-for-sale investments, which consist of mutual funds that invest primarily in debt instruments:

	<b>June 30, 2007</b>	<b>June 30, 2006</b>
Cost	\$ 2,323,642	\$ 2,385,570
Gross unrealized losses	-	(54,736)
Fair value	\$ 2,323,642	\$ 2,330,834

The Company recorded realized losses of \$61,928, \$0 and \$114,551 in its statement of operations for the years ended June 30, 2007, 2006 and 2005, respectively, upon determining that certain previously-unrealized losses were other than temporary, and reduced the cost basis of the underlying securities accordingly.

**(6) PROPERTY AND EQUIPMENT, NET**

Property and equipment, net, consists of the following:

	<b>June 30, 2007</b>	<b>June 30, 2006</b>
Office equipment	\$ 1,928,219	\$ 1,758,232
Laboratory equipment	3,695,680	3,041,209
Leasehold improvements	7,066,008	6,766,782
	12,689,906	11,566,223
Less: Accumulated depreciation and amortization	(6,619,680)	(5,218,518)
	\$ 6,070,226	\$ 6,347,705

The cost of assets acquired under capital leases amounted to \$663,612 and \$438,250 as of June 30, 2007 and 2006, respectively. Accumulated amortization associated with assets acquired under capital leases amounted to \$189,984 and \$79,115 as of June 30, 2007 and 2006, respectively.



Table of Contents (Financial)**(7) ACCRUED EXPENSES**

Accrued expenses consist of the following:

	<b>June 30, 2007</b>	<b>June 30, 2006</b>
Clinical study costs	\$ 147,798	\$ 893,041
Formulation development	203,250	1,000,000
Other operating expenses	635,810	1,146,635
Deferred rent, current portion	959,303	852,546
Other	474,676	574,206
	<b>\$ 2,420,837</b>	<b>\$ 4,466,428</b>

**(8) COMMITMENTS AND CONTINGENCIES**

*Leases* The Company currently leases facilities under three non-cancelable operating leases. Future minimum lease payments under these leases are as follows:

<b>Year Ending June 30,</b>	
2008	\$ 2,572,281
2009	1,511,736
2010	1,514,345
2011	1,540,148
2012	1,541,549
Thereafter	755,886

For the years ended June 30, 2007, 2006 and 2005, rent expense was \$1,657,842, \$1,630,165 and \$897,856, respectively.

*Capital Leases and Notes Payable* The Company has acquired certain of its laboratory equipment under leases classified as capital leases and with financing agreements. Scheduled future payments related to notes payable and capital leases as of June 30, 2007 are as follows:

<b>Year Ending June 30,</b>	
2008	\$243,557
2009	188,891
2010	83,372
2011	22,264
2012	16,699
Total	554,783
Amount representing interest	(62,816)
Net	\$491,967

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

*License Agreements* The Company has a license agreement for patent rights related to certain compounds and methods of treatment for sexual dysfunction that requires minimum payments of \$150,000 per year. The license agreement requires contingent payments based on certain up-front fees the Company receives as a result of a sublicense. The Company does not reasonably expect to sublicense such rights or make any material contingent payments during the next twelve months.

The Company has license agreements related to NeutroSpec that require minimum annual payments of \$25,000, royalty payments on commercial net sales and payments of up to \$2,250,000



Table of Contents (Financial)

contingent on the achievement of specified cumulative net margins on sales. No royalty payments or other contingent amounts will be payable under these agreements unless the Company recommences sales and marketing of NeutroSpec. The Company does not reasonably expect to make any such contingent payments during the next twelve months.

*Employee Retirement Savings Plan* The Company maintains a defined contribution 401(k) plan for the benefit of its employees. The Company currently matches a portion of employee contributions to the plan. In the years ended June 30, 2007, 2006 and 2005, Company contributions amounted to \$211,778, \$180,248 and \$149,236, respectively.

*Contingencies* The Company accounts for litigation losses in accordance with SFAS 5, Accounting for Contingencies. Under SFAS 5, loss contingency provisions are recorded for probable losses when management is able to reasonably estimate the loss. Any outcome upon settlement that deviates from the Company's best estimate may result in additional expense or in a reduction in expense in a future accounting period. The Company records legal expenses associated with such contingencies as incurred.

Competitive Technologies, Inc. (CTI) initiated arbitration proceedings with the Company for breach of the terms of its license agreement for patent rights related to certain compounds and methods of treatment for sexual dysfunction and for other actions asserted to arise out of the license agreement. CTI also alleges that the Company committed certain tortious acts against CTI, including fraud and negligent misrepresentation relating to entering into the license agreement originally and tortious interference with business expectancy concerning termination by the Company and King of the sublicense of the CTI license agreement to King. CTI is seeking unspecified damages in excess of \$500,000. In addition, CTI seeks a declaration that bremelanotide is covered by the license agreement. The Company filed a reply to CTI's statement of claim, denying all material allegations asserted by CTI, and asserting counterclaims against CTI for declaratory judgment that claims are barred by the previous settlement agreement with CTI and that bremelanotide is not subject to the license agreement with CTI. The license agreement provides for binding arbitration as the remedy for dispute resolution. Motions for summary adjudication of certain claims have been filed by the Company and CTI, and limited discovery has been conducted relating to the motions. Oral argument on the motions for summary adjudication is scheduled in the second half of calendar 2007, with a hearing on the merits, if required, currently scheduled for the first half of calendar 2008.

CTI also initiated litigation against the Company by filing a suit in Connecticut Superior Court for breach of the settlement agreement of an earlier arbitration between CTI and the Company. CTI generally asserted that the Company failed to timely register for resale shares of its common stock valued at approximately \$300,000 issued to CTI in the settlement, and additionally asserted claims for breach of implied warranties, unfair trade practices, fraudulent inducement, fraudulent non-disclosure and fraud. The Company denied all material allegations of CTI's claims and asserted defenses and counterclaims against CTI for fraud, fraudulent inducement, unfair trade practices, breach of the settlement agreement and declaratory judgment that under the settlement the Company was released from any further obligations to CTI relating to payments the Company may receive from King concerning bremelanotide, that CTI should be compelled to comply with the settlement agreement and withdraw its earlier arbitration request, or alternatively that the settlement agreement of the earlier arbitration should be set aside. CTI filed a reply generally denying the Company's counterclaims and asserting defenses. Discovery has been initiated by both CTI and the Company.

On September 10, 2007 the Company received a Notice of Termination of the License Agreement from CTI, asserting a breach of the license agreement relating to the Company's agreement with King, and seeking termination of the license agreement with CTI. The Notice further provides sixty days for the Company to cure the asserted breach or otherwise respond.

The Company cannot reasonably predict the outcome of the disputes or reasonably estimate the range of potential loss, if any. Although the amount of any liability that could arise with respect to these matters cannot be predicted, the Company does not believe that the resolution of these matters will have a material adverse effect on its financial position, results of operations or liquidity.

The Company is subject to an inherent risk of product liability claims as a result of the testing and marketing of its products. In December 2005, as a result of safety concerns raised in connection with the use of NeutroSpec, the Company and Mallinckrodt suspended NeutroSpec sales and marketing activities. If any claim is asserted based on the use of NeutroSpec, the Company may incur future expenses or losses in connection with the related litigation.

Table of Contents (Financial)**(9) STOCKHOLDERS EQUITY**

*Series A Convertible Preferred Stock* As of June 30, 2007, 4,997 shares of Series A Convertible Preferred Stock were outstanding. Each share of Series A Convertible Preferred Stock is convertible at any time, at the option of the holder, into the number of shares of common stock equal to \$100 divided by the Series A Conversion Price. As of June 30, 2007, the Series A Conversion Price is \$2.51, so each share of Series A Convertible Preferred Stock is currently convertible into approximately 40 shares of common stock. The Series A Conversion Price is subject to adjustment, under certain circumstances, upon the sale or issuance of common stock for consideration per share less than either (i) the Series A Conversion Price in effect on the date of such sale or issuance, or (ii) the market price of the common stock as of the date of such sale or issuance. The Series A Conversion Price is also subject to adjustment upon the occurrence of a merger, reorganization, consolidation, reclassification, stock dividend or stock split which will result in an increase or decrease in the number of shares of common stock outstanding. Shares of Series A Convertible Preferred Stock have a preference in liquidation, including certain merger transactions, of \$100 per share, or \$499,700 in the aggregate as of June 30, 2007.

*Common Stock Transactions* In August 2004, upon the signing of the Company's collaborative development and marketing agreement with King, the Company issued to King 1,176,125 shares of common stock and three-year warrants to purchase 235,225 shares of common stock at an exercise price of \$4.25 per share. Of the \$20,000,000 aggregate payment received from King upon signing, \$3,606,672 was allocated to the shares and warrants based on their estimated fair market value. In September 2005, the Company sold to King 4,499,336 shares of its common stock and three-year warrants to purchase 719,894 shares of common stock at an exercise price of \$2.22 per share for an aggregate purchase price of \$10,000,000. The sale of the stock and warrants was made pursuant to the Company's collaborative development and marketing agreement with King.

In April 2006, the Company sold 10,978,677 units in a private placement for a total purchase price of \$26,800,000. Each unit consisted of one share of its common stock and a five-year warrant to purchase 0.30 shares of common stock at an exercise price of \$2.88 per share. Net proceeds to the Company, after offering costs, amounted to approximately \$24,800,000.

In February 2007, the Company completed the sale of 13,750,000 shares of common stock in a registered direct offering. Net proceeds to the Company, after costs of the offering, amounted to approximately \$25,500,000.

*Outstanding Stock Purchase Warrants* As of June 30, 2007, the Company had outstanding warrants exercisable for shares of common stock as follows:

<b>Shares of Common Stock</b>	<b>Exercise Price per Share</b>	<b>Latest Termination Date</b>
25,752	\$1.37	07/29/07
51,502	1.46	07/29/07
823,758	1.54	11/29/07
2,464,789	1.77	03/21/08
719,894	2.22	09/26/08
182,705	2.75	07/29/07
15,000	2.82	05/13/12
3,293,591	2.88	04/17/11
50,000	2.97	11/30/07
25,000	3.38	11/30/07
15,000	4.00	12/15/10
1,041,750	4.06	01/28/09
235,225	4.25	08/18/07
8,943,966		

In November 2004, the Company issued warrants to purchase 75,000 shares of common stock at prices between \$2.97 and \$3.375 per share as partial consideration for financial advisory services rendered during the year ended June 30, 2005. The warrants expire in November 2007. The fair value of these

Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

Table of Contents (Financial)

warrants of approximately \$101,000, as calculated by the Black-Scholes option pricing model, is included in general and administrative expenses in the year ended June 30, 2005.

*Stock Plan* The Company's 2005 Stock Plan was approved by the Company's stockholders in June 2005 and provides for incentive and nonqualified stock option grants and other stock-based awards to employees, non-employee directors and consultants for up to 5,000,000 shares of common stock. The 2005 Stock Plan is administered under the direction of the Board of Directors, which may specify grant terms and recipients. Options granted by the Company generally expire ten years from the date of grant and generally vest over three to four years. As of June 30, 2007, 2,795,777 shares were available for grant under the 2005 Stock Plan.

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

The following table summarizes option activity for the years ended June 30, 2007, 2006 and 2005:

	2007		2006		2005	
	Number of <u>Shares</u>	Weighted Average Exercise <u>Price</u>	Number of <u>Shares</u>	Weighted Average Exercise <u>Price</u>	Number of <u>Shares</u>	Weighted Average Exercise <u>Price</u>
Outstanding at beginning of year	5,659,302	\$3.12	4,688,152	\$3.41	4,365,601	\$3.58
Granted	1,406,975	2.10	1,276,297	2.10	661,933	2.45
Forfeited	(260,520)	1.99	(149,527)	2.33	(69,134)	3.50
Exercised	(78,460)	1.48	(21,162)	1.64	(35,000)	1.69
Expired	(332,577)	4.52	(134,458)	4.23	(235,248)	4.15
Outstanding at end of year	6,394,720	2.89	5,659,302	3.12	4,688,152	3.41
Exercisable at end of year	4,549,759	3.18	4,267,879	3.41	3,830,910	3.61
Weighted average fair value of options granted during the year		\$1.52		\$1.38		\$1.92

The following table summarizes options outstanding as of June 30, 2007:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Term	Aggregate Intrinsic Value
Options outstanding at end of year	6,394,720	\$2.89	6.4	\$375,644
Options vested and exercisable at end of year	4,549,759	3.18	5.4	273,640
Unvested options expected to vest	1,645,326	2.20	8.7	91,940

The intrinsic value of options exercised in the years ended June 30, 2007, 2006 and 2005 was \$64,395, \$21,368 and \$32,384, respectively.

The fair value of option grants is estimated at the grant date using the Black-Scholes model. For grants during the year ended June 30, 2007, the Company's weighted average assumptions for expected



## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

### Table of Contents (Financial)

volatility, dividends, term and risk-free interest rate were 80%, 0%, 6.2 years and 4.9%, respectively. For grants during the year ended June 30, 2006, the Company's weighted average assumptions for expected volatility, dividends, term and risk-free interest rate were 85%, 0%, 6.6 years and 4.0%, respectively. Expected volatilities are based primarily on the Company's historical volatility. The expected term of options is estimated based on the Company's historical exercise and employment termination experience determined separately for certain employee groups. The risk-free interest rate is based on U.S. Treasury yields for securities with terms approximating the expected term of the option.

In the years ended June 30, 2007 and 2006, in accordance with SFAS 123(R), the Company recorded stock-based compensation related to stock options of \$1,223,481 and \$1,167,177, respectively, representing approximately \$0.02 per share in each year. The Company did not record a tax benefit related to stock-based compensation expense. As of June 30, 2007, there was \$1,744,164 of total unrecognized compensation cost related to unvested options, which is expected to be recognized over a weighted-average period of 1.4 years.

During the year ended June 30, 2005, in accordance with APB 25, the Company reversed \$15,879 of previously-recognized stock-based compensation expense as a result of remeasuring certain modified and performance-based options.

As of June 30, 2007, options for 50,000 shares at an exercise price of \$1.99 per share were subject to vesting contingent on achievement of certain performance conditions.

### *Restricted Stock Units*

In October 2006, the Company made grants of restricted stock units to three executives for an aggregate of 975,000 shares of common stock. Of the total shares, 325,000 will vest if the quoted market price of Palatin's common stock is \$4.00 or more for twenty consecutive trading days, an additional 325,000 will vest if the quoted market price of Palatin's common stock is \$6.00 or more for twenty consecutive trading days and the remaining 325,000 will vest if the quoted market price of Palatin's common stock is \$8.00 or more for twenty consecutive trading days. The restricted stock units can only vest while the executives are employed by the Company and unvested units expire four years from the date of grant. The restricted stock units also require that each grantee retain ownership of at least 33% of any vested stock for the duration of the executive's employment with the Company.

The fair value of the restricted stock units was estimated at the grant date using a lattice-type model. The Company's assumptions for expected volatility, dividends and risk-free rate were 80%, 0% and 4.56%, respectively. The expected volatility is based on the Company's historical volatility and the risk-free rate is based on U.S. Treasury yields for securities with terms approximating the contractual term of the units. The aggregate estimated fair value of the grants at the date of grant was approximately \$1,800,000, which is expected to be recognized over a weighted-average period of approximately three years. In the year ended June 30, 2007, the Company recognized \$503,344 of share-based compensation expense related to the grants. The amount and timing of such compensation expense to be recorded in future periods may be affected by grantee terminations and certain changes in the Company's share price.

## **(10) INCOME TAXES**

The Company has had no income tax expense or benefit since inception because of operating losses, except for amounts recognized for sales of New Jersey state operating loss carryforwards. Deferred tax assets and liabilities are determined based on the estimated future tax effect of differences between the financial statements and tax reporting basis of assets and liabilities, as well as for operating loss carryforwards and research and development credits, given the provisions of existing tax laws.

As of June 30, 2007, the Company had federal and state net operating loss carryforwards of approximately \$163,000,000 and \$113,000,000, respectively, which expire between 2008 and 2027 if not utilized. As of June 30, 2007 the Company had federal research and development credits of approximately \$4,500,000 that will begin to expire in 2012, if not utilized.

The Tax Reform Act of 1986 (the Act) provides for limitation on the use of net operating loss and research and development tax credit carryforwards following certain ownership changes (as defined by the Act) that could limit the Company's ability to utilize these carryforwards. The Company may have experienced various ownership changes, as defined by the Act, as a result of past financings. Accordingly,

Table of Contents (Financial)

the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes; therefore the Company may not be able to take full advantage of these carryforwards for federal and state income tax purposes.

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

	<b>June 30, 2007</b>	<b>June 30, 2006</b>
Net operating loss carryforwards	\$ 63,610,000	\$ 55,199,000
Research and development tax credits	4,513,000	3,967,000
Accrued expenses, deferred revenue and other	8,569,000	5,091,000
	76,692,000	64,257,000
Valuation allowances	(76,692,000)	(64,257,000)
Net deferred tax assets	\$ -	\$ -

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income and the application of loss limitation provisions related to ownership changes. Due to the Company's history of losses, the deferred tax assets are fully offset by a valuation allowance as of June 30, 2007 and 2006. The valuation allowance for the years ended June 30, 2007, 2006 and 2005 increased by \$12,435,000, \$11,261,000 and \$6,468,000, respectively, related primarily to additional net operating losses incurred by the Company and the tax treatment of certain deferred revenue.

During the years ended June 30, 2007, 2006 and 2005, the Company sold New Jersey state net operating loss carryforwards, which resulted in the recognition of \$778,308, \$666,275 and \$580,275, respectively, in tax benefits.

**(11) SUBSEQUENT EVENTS**

In September 2007, the Company received notice from King terminating the Collaborative Development and Marketing Agreement between the Company and King, in accordance with its terms, effective December 5, 2007. The notice followed communication with representatives of the FDA, which raised serious concerns about the benefits and risks of the progression of bremelanotide into Phase 3 clinical studies for erectile dysfunction. Upon termination, Palatin will solely own all rights to bremelanotide without any obligation for future payments to King, other than any amounts payable for the reimbursement of bremelanotide costs incurred by King prior to termination. King has no obligation for future payments to Palatin, other than any amounts payable for the reimbursement of bremelanotide costs incurred by Palatin prior to termination.

In connection with the termination of the agreement, the Company expects to recognize in its fiscal year ending June 30, 2008 all remaining deferred up-front license fees received from King, together with associated deferred costs, which prior to termination were being recognized as revenues and costs over the estimated period of the Company's performance under the agreement. As of June 30, 2007, deferred revenue and deferred costs, included in other current assets and other assets, amounted to \$7,064,996 and \$886,479, respectively.



Table of Contents (Financial)**(12) CONSOLIDATED QUARTERLY FINANCIAL DATA UNAUDITED**

The following tables provide quarterly data for the years ended June 30, 2007 and 2006:

	<b>Three Months Ended</b>			
	<b>June 30, 2007</b>	<b>March 31, 2007</b>	<b>December 31, 2006</b>	<b>September 30, 2006</b>
	(amounts in thousands, except per share data)			
Total revenues	\$ 2,638	\$ 3,090	\$ 3,743	\$ 4,935
Total operating expenses	9,147	10,150	11,224	13,686
Total other income, net	404	339	214	314
Loss before income taxes	(6,105)	(6,721)	(7,267)	(8,437)
Income tax benefit	-	-	778	-
Net loss	\$ (6,105)	\$ (6,721)	\$ (6,489)	\$ (8,437)
Basic and diluted net loss per common share	\$ (0.07)	\$ (0.09)	\$ (0.09)	\$ (0.12)
Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share	84,965,331	78,052,712	71,055,893	70,878,521

	<b>Three Months Ended</b>			
	<b>June 30, 2006</b>	<b>March 31, 2006</b>	<b>December 31, 2005</b>	<b>September 30, 2005</b>
	(amounts in thousands, except per share data)			
Total revenues	\$ 4,973	\$ 5,045	\$ 4,587	\$ 5,144
Cost of product sales	-	-	2,041	-
Royalties	-	-	117	183
Other operating expenses	13,196	12,793	10,750	11,119
Total other income, net	346	146	211	122
Loss before income taxes	(7,877)	(7,602)	(8,110)	(6,036)
Income tax benefit	-	-	666	-
Net loss	\$ (7,877)	\$ (7,602)	\$ (7,444)	\$ (6,036)
Basic and diluted net loss per common share	\$ (0.11)	\$ (0.13)	\$ (0.13)	\$ (0.11)
Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share	68,948,204	59,339,220	58,869,492	54,488,412

Table of Contents

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

**Item 9A. Controls and Procedures.**

Our management carried out an evaluation, with the participation of our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) of the Exchange Act) as of the end of the period covered by this report. Based upon this evaluation, our Chief Executive Officer and our Chief Financial Officer concluded that, as of June 30, 2007, our disclosure controls and procedures were effective.

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

*Management's Report on Internal Control Over Financial Reporting*

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

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

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

Palatin's management assessed the effectiveness of the Company's internal control over financial reporting as of June 30, 2007. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on its assessment, management believes that, as of June 30, 2007, the Company's internal control over financial reporting is effective based on those criteria.

Palatin's independent registered public accounting firm has issued an audit report on management's assessment of the Company's internal control over financial reporting. This report appears below.

*Report Of Independent Registered Public Accounting Firm*

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

We have audited management's assessment, included in Management's Report on Internal Control Over Financial Reporting presented above, that Palatin Technologies, Inc. maintained effective internal control over financial reporting as of June 30, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Palatin Technologies, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Table of Contents

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Palatin Technologies, Inc. maintained effective internal control over financial reporting as of June 30, 2007, is fairly stated, in all material respects, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, Palatin Technologies, Inc. maintained, in all material respects, effective internal control over financial reporting as of June 30, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Palatin Technologies, Inc. and subsidiary as of June 30, 2007 and 2006, 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, 2007, and our report dated September 12, 2007 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Philadelphia, Pennsylvania  
September 12, 2007

**Item 9B. Other Information.**

None.

Table of Contents

**PART III**

The information required by Part III of Form 10-K under

Item 10 - Directors, Executive Officers and Corporate Governance

Item 11 - Executive Compensation

Item 12 - Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters, except for the information required by Regulation S-K, Item 201(d), which is set forth under Item 5 of this report

Item 13 - Certain Relationships and Related Transactions, and Director Independence

Item 14 - Principal Accountant Fees and Services

is incorporated by reference from our definitive proxy statement relating to the 2007 Annual Meeting of Stockholders, which we will file with the SEC within 120 days after our June 30, 2007 fiscal year end.

Table of Contents

**PART IV**

**Item 15. Exhibits and Financial Statement Schedules.**

**(a) Documents filed as part of the report:**

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

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statements of Cash Flows

Consolidated Statements of Stockholders' Equity

Notes to Consolidated Financial Statements

2. Financial statement schedules: None.

3. Exhibits:

No.      Description

- 3.01 Restated certificate of incorporation. Incorporated by reference to Exhibit 3.01 of our quarterly report on Form 10-Q for the quarter ended March 31, 2005, filed with the SEC on May 9, 2005.
- 3.02 Bylaws. Incorporated by reference to Exhibit 3.2 of our quarterly report on Form 10-QSB for the quarter ended December 31, 1997, filed with the SEC on February 13, 1998.
- 10.02 1996 Stock Option Plan, as amended effective January 1, 2001. Incorporated by reference to Exhibit 4.1 of our registration statement on Form S-8, Commission File No. 333-83876, filed with the SEC on March 6, 2002.
- 10.03 Carl Spana Stock Option Agreement. Incorporated by reference to Exhibit 4.15 of our registration statement on Form S-8, Commission File No. 333-57079, filed with the SEC on June 17, 1998.
- 10.04 Executive Officers Stock Option Agreement. Incorporated by reference to Exhibit 4.18 of our registration statement on Form S-8, Commission File No. 333-57079, filed with the SEC on June 17, 1998.
- 10.06 Strategic Collaboration Agreement dated as of August 17, 1999, between Palatin and Mallinckrodt, Inc. Incorporated by reference to Exhibit 10.21 of our amended annual report on Form 10-KSB/A for the year ended June 30, 1999, filed with the SEC on December 28, 1999.
- 10.07 Amendment To Strategic Collaboration Agreement dated as of May 13, 2002 between Palatin and Mallinckrodt, Inc. Incorporated by reference to Exhibit 10.1 of our quarterly report on Form 10-Q for the quarter ended March 31, 2002, filed with the SEC on May 15, 2002. We have obtained confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
- 10.15 Form of registration rights agreement for our October 2001 private placement. Incorporated by reference to Exhibit 10.2 of our quarterly report on Form 10-Q for the quarter ended September 30, 2001, filed with the SEC on November 14, 2001.

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

- 10.17 Form of stock purchase agreement for our June-July 2002 private placement. Incorporated by reference to Exhibit 10.27 of our annual report on Form 10-K for the year ended June 30, 2002, filed with the SEC on September 30, 2002.
- 10.18 Form of registration rights agreement for our June-July 2002 private placement. Incorporated by reference to Exhibit 10.28 of our annual report on Form 10-K for the year ended June 30, 2002, filed with the SEC on September 30, 2002.
- 10.19 Form of warrant issued to purchasers in our June-July 2002 private placement. Incorporated by reference to Exhibit 10.29 of our annual report on Form 10-K for the year ended June 30, 2002, filed with the SEC on September 30, 2002.

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

### Table of Contents

- 10.20 Form of stock purchase agreement for our November 2002 private placement. Incorporated by reference to Exhibit 10.30 of our annual report on Form 10-K for the year ended June 30, 2003, filed with the SEC on September 29, 2003.
- 10.21 Form of registration rights agreement for our November 2002 private placement. Incorporated by reference to Exhibit 10.31 of our annual report on Form 10-K for the year ended June 30, 2003, filed with the SEC on September 29, 2003.
- 10.22 Form of warrant issued to purchasers in our November 2002 private placement. Incorporated by reference to Exhibit 10.32 of our annual report on Form 10-K for the year ended June 30, 2003, filed with the SEC on September 29, 2003.
- 10.23 Form of stock purchase agreement for our March 2003 private placement. Incorporated by reference to Exhibit 10.33 of our annual report on Form 10-K for the year ended June 30, 2003, filed with the SEC on September 29, 2003.
- 10.24 Form of warrant issued to purchasers in our March 2003 private placement. Incorporated by reference to Exhibit 10.34 of our annual report on Form 10-K for the year ended June 30, 2003, filed with the SEC on September 29, 2003.
- 10.25 Form of stock purchase agreement, including warrant certificate, for our January 2004 private placement. Incorporated by reference to Exhibit 10.01 of our quarterly report on Form 10-Q for the quarter ended December 31, 2003, filed with the SEC on February 17, 2004.
- 10.27 Securities Purchase Agreement between Palatin and King Pharmaceuticals, Inc. Incorporated by reference to Exhibit 10.27 of our annual report on Form 10-K for the year ended June 30, 2004, filed with the SEC on September 13, 2004. We have requested confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
- 10.28 Collaborative Development and Marketing Agreement between Palatin and King Pharmaceuticals, Inc. Incorporated by reference to Exhibit 10.28 of our annual report on Form 10-K for the year ended June 30, 2004, filed with the SEC on September 13, 2004. We have requested confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
- 10.29 Form of warrant certificate issued to King Pharmaceuticals, Inc. Incorporated by reference to Exhibit 10.29 of our annual report on Form 10-K for the year ended June 30, 2004, filed with the SEC on September 13, 2004.
- 10.31 2005 Stock Plan. Incorporated by reference to Exhibit 10.01 of our current report on Form 8-K, filed with the SEC on June 10, 2005.
- 10.32 Amendment to Strategic Collaboration Agreement dated as of October 1, 2005, between Palatin and Mallinckrodt, Inc. Incorporated by reference to Exhibit 10.32 of our quarterly report on Form 10-Q for the quarter ended September 30, 2005, filed with the SEC on November 8, 2005. We have requested confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
- 10.36 Form of Option Certificate (incentive option) under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.1 of our current report on Form 8-K, filed with the SEC on September 21, 2005.
- 10.37 Form of Incentive Stock Option Agreement Standard under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.2 of our current report on Form 8-K, filed with the SEC on September 21, 2005.
- 10.38 Form of Option Certificate (non-qualified option) under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.3 of our current report on Form 8-K, filed with the SEC on September 21, 2005.
- 10.39 Form of Non-Qualified Stock Option Agreement under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.4 of our current report on Form 8-K, filed with the SEC on September 21, 2005.

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

### Table of Contents

- 10.40 Second Amendment and Agreement dated as of December 16, 2005 amending the Collaborative Development and Marketing Agreement between Palatin and King Pharmaceuticals, Inc. dated August 12, 2004. Incorporated by reference to Exhibit 10.1 of our current report on Form 8-K, filed with the SEC on December 23, 2005.
- 10.41 Form of stock purchase agreement for our April 2006 private placement. Incorporated by reference to Exhibit 10.2 of our current report on Form 8-K, filed with the SEC on April 12, 2006.
- 10.42 Form of warrant issued to purchasers in our April 2006 private placement. Incorporated by reference to Exhibit 10.3 of our current report on Form 8-K, filed with the SEC on April 12, 2006.
- 10.43 Restricted Stock Unit Agreement. Incorporated by reference to Exhibit 10.1 of our quarterly report on Form 10-Q for the quarter ended December 31, 2006, filed with the SEC on February 8, 2007.
- 10.44 Research Collaboration and License Agreement dated January 30, 2007, between Palatin and AstraZeneca AB. Incorporated by reference to Exhibit 10.2 of our quarterly report on Form 10-Q for the quarter ended December 31, 2006, filed with the SEC on February 8, 2007. We have requested confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
- 10.45 Employment Agreement dated as of July 1, 2007 between Palatin and Carl Spana. \*
- 10.46 Employment Agreement dated as of July 1, 2007 between Palatin and Stephen T. Wills. \*
- 10.47 Employment Agreement dated as of May 1, 2007, between Palatin and Trevor Hallam. \*
- 21 Subsidiaries of the registrant. \*
- 23 Consent of KPMG LLP. \*
- 31.1 Certification of Chief Executive Officer. \*
- 31.2 Certification of Chief Financial Officer. \*
- 32.1 Certification of principal executive officer pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. \*
- 32.2 Certification of principal financial officer pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. \*

---

\* Exhibit filed with this report.

Management contract or compensatory plan or arrangement.



Table of Contents**SIGNATURES**

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

**PALATIN TECHNOLOGIES, INC.**

By: /s/ Carl Spana  
 Carl Spana, Ph.D.  
 President and Chief Executive Officer

Date: September 12, 2007

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

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ Carl Spana</u> Carl Spana	President, Chief Executive Officer and Director (principal executive officer)	September 12, 2007
<u>/s/ Stephen T. Wills</u> Stephen T. Wills	Executive Vice President and Chief Financial Officer (principal financial and accounting officer)	September 12, 2007
<u>/s/ John K.A. Prendergast</u> John K.A. Prendergast	Chairman and Director	September 12, 2007
<u>/s/ Perry B. Molinoff</u> Perry B. Molinoff	Director	September 12, 2007
<u>/s/ Robert K. deVeer, Jr.</u> Robert K. deVeer, Jr.	Director	September 12, 2007
<u>/s/ Zola P. Horovitz</u> Zola P. Horovitz	Director	September 12, 2007
<u>/s/ Robert I. Taber</u> Robert I. Taber	Director	September 12, 2007
<u>/s/ Errol DeSouza</u> Errol DeSouza	Director	September 12, 2007
<u>/s/ J. Stanley Hull</u> J. Stanley Hull	Director	September 12, 2007

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

### Table of Contents

#### EXHIBIT LIST

<u>No.</u>	<u>Description</u>
3.01	Restated certificate of incorporation. Incorporated by reference to Exhibit 3.01 of our quarterly report on Form 10-Q for the quarter ended March 31, 2005, filed with the SEC on May 9, 2005.
3.02	Bylaws. Incorporated by reference to Exhibit 3.2 of our quarterly report on Form 10-QSB for the quarter ended December 31, 1997, filed with the SEC on February 13, 1998.
10.02	1996 Stock Option Plan, as amended effective January 1, 2001. Incorporated by reference to Exhibit 4.1 of our registration statement on Form S-8, Commission File No. 333-83876, filed with the SEC on March 6, 2002.
10.03	Carl Spana Stock Option Agreement. Incorporated by reference to Exhibit 4.15 of our registration statement on Form S-8, Commission File No. 333-57079, filed with the SEC on June 17, 1998.
10.04	Executive Officers Stock Option Agreement. Incorporated by reference to Exhibit 4.18 of our registration statement on Form S-8, Commission File No. 333-57079, filed with the SEC on June 17, 1998.
10.06	Strategic Collaboration Agreement dated as of August 17, 1999, between Palatin and Mallinckrodt, Inc. Incorporated by reference to Exhibit 10.21 of our amended annual report on Form 10-KSB/A for the year ended June 30, 1999, filed with the SEC on December 28, 1999.
10.07	Amendment To Strategic Collaboration Agreement dated as of May 13, 2002 between Palatin and Mallinckrodt, Inc. Incorporated by reference to Exhibit 10.1 of our quarterly report on Form 10-Q for the quarter ended March 31, 2002, filed with the SEC on May 15, 2002. We have obtained confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
10.15	Form of registration rights agreement for our October 2001 private placement. Incorporated by reference to Exhibit 10.2 of our quarterly report on Form 10-Q for the quarter ended September 30, 2001, filed with the SEC on November 14, 2001.
10.17	Form of stock purchase agreement for our June-July 2002 private placement. Incorporated by reference to Exhibit 10.27 of our annual report on Form 10-K for the year ended June 30, 2002, filed with the SEC on September 30, 2002.
10.18	Form of registration rights agreement for our June-July 2002 private placement. Incorporated by reference to Exhibit 10.28 of our annual report on Form 10-K for the year ended June 30, 2002, filed with the SEC on September 30, 2002.
10.19	Form of warrant issued to purchasers in our June-July 2002 private placement. Incorporated by reference to Exhibit 10.29 of our annual report on Form 10-K for the year ended June 30, 2002, filed with the SEC on September 30, 2002.
10.20	Form of stock purchase agreement for our November 2002 private placement. Incorporated by reference to Exhibit 10.30 of our annual report on Form 10-K for the year ended June 30, 2003, filed with the SEC on September 29, 2003.
10.21	Form of registration rights agreement for our November 2002 private placement. Incorporated by reference to Exhibit 10.31 of our annual report on Form 10-K for the year ended June 30, 2003, filed with the SEC on September 29, 2003.
10.22	Form of warrant issued to purchasers in our November 2002 private placement. Incorporated by reference to Exhibit 10.32 of our annual report on Form 10-K for the year ended June 30, 2003, filed with the SEC on September 29, 2003.
10.23	Form of stock purchase agreement for our March 2003 private placement. Incorporated by reference to Exhibit 10.33 of our annual report on Form 10-K for the year ended June 30, 2003, filed with the SEC on September 29, 2003.
10.24	Form of warrant issued to purchasers in our March 2003 private placement. Incorporated by reference to Exhibit 10.34 of our annual report on Form 10-K for the year ended June 30, 2003, filed with the SEC on September 29, 2003.

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

- 10.25 Form of stock purchase agreement, including warrant certificate, for our January 2004 private placement. Incorporated by reference to Exhibit 10.01 of our quarterly report on Form 10-Q for the quarter ended December 31, 2003, filed with the SEC on February 17, 2004.
- 10.27 Securities Purchase Agreement between Palatin and King Pharmaceuticals, Inc. Incorporated by reference to Exhibit 10.27 of our annual report on Form 10-K for the year ended June 30, 2004, filed with the SEC on September 13, 2004. We have requested confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
- 10.28 Collaborative Development and Marketing Agreement between Palatin and King Pharmaceuticals, Inc. Incorporated by reference to Exhibit 10.28 of our annual report on Form 10-K for the year ended June 30, 2004, filed with the SEC on September 13, 2004. We have requested confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
- 10.29 Form of warrant certificate issued to King Pharmaceuticals, Inc. Incorporated by reference to Exhibit 10.29 of our annual report on Form 10-K for the year ended June 30, 2004, filed with the SEC on September 13, 2004.
- 10.31 2005 Stock Plan. Incorporated by reference to Exhibit 10.01 of our current report on Form 8-K, filed with the SEC on June 10, 2005.
- 10.32 Amendment to Strategic Collaboration Agreement dated as of October 1, 2005, between Palatin and Mallinckrodt, Inc. Incorporated by reference to Exhibit 10.32 of our quarterly report on Form 10-Q for the quarter ended September 30, 2005, filed with the SEC on November 8, 2005. We have requested confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
- 10.36 Form of Option Certificate (incentive option) under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.1 of our current report on Form 8-K, filed with the SEC on September 21, 2005.
- 10.37 Form of Incentive Stock Option Agreement Standard under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.2 of our current report on Form 8-K, filed with the SEC on September 21, 2005.
- 10.38 Form of Option Certificate (non-qualified option) under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.3 of our current report on Form 8-K, filed with the SEC on September 21, 2005.
- 10.39 Form of Non-Qualified Stock Option Agreement under the 2005 Stock Plan. Incorporated by reference to Exhibit 10.4 of our current report on Form 8-K, filed with the SEC on September 21, 2005.
- 10.40 Second Amendment and Agreement dated as of December 16, 2005 amending the Collaborative Development and Marketing Agreement between Palatin and King Pharmaceuticals, Inc. dated August 12, 2004. Incorporated by reference to Exhibit 10.1 of our current report on Form 8-K, filed with the SEC on December 23, 2005.
- 10.41 Form of stock purchase agreement for our April 2006 private placement. Incorporated by reference to Exhibit 10.2 of our current report on Form 8-K, filed with the SEC on April 12, 2006.
- 10.42 Form of warrant issued to purchasers in our April 2006 private placement. Incorporated by reference to Exhibit 10.3 of our current report on Form 8-K, filed with the SEC on April 12, 2006.
- 10.43 Restricted Stock Unit Agreement. Incorporated by reference to Exhibit 10.1 of our quarterly report on Form 10-Q for the quarter ended December 31, 2006, filed with the SEC on February 8, 2007.
- 10.44 Research Collaboration and License Agreement dated January 30, 2007, between Palatin and AstraZeneca AB. Incorporated by reference to Exhibit 10.2 of our quarterly report on Form 10-Q for the quarter ended December 31, 2006, filed with the SEC on February 8, 2007. We have requested confidential treatment of certain provisions contained in this exhibit. The copy filed as an exhibit omits the information subject to the confidentiality request.
- 10.45 Employment Agreement dated as of July 1, 2007 between Palatin and Carl Spana. \*
- 10.46 Employment Agreement dated as of July 1, 2007 between Palatin and Stephen T. Wills. \*

## Edgar Filing: PALATIN TECHNOLOGIES INC - Form 10-K

- 10.47 Employment Agreement dated as of May 1, 2007, between Palatin and Trevor Hallam. \*
- 21 Subsidiaries of the registrant. \*
- 23 Consent of KPMG LLP. \*
- 31.1 Certification of Chief Executive Officer. \*
- 31.2 Certification of Chief Financial Officer. \*
- 32.1 Certification of principal executive officer pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. \*
- 32.2 Certification of principal financial officer pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. \*

---

\* Exhibit filed with this report.

Management contract or compensatory plan or arrangement.