

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Palatin Technologies, Inc.

Form: 10-K

Date Filed: 2005-09-13

Corporate Issuer CIK: 911216

Symbol: PTN

Fiscal Year End: 6/30

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, 2005

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 Cedarbrook 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:

Common Stock, par value \$.01 per share
(Title of class)

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

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 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.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes No

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately \$121,604,000, computed by reference to the price at which the common stock was last sold on December 31, 2004.

As of September 1, 2005, 54,240,246 shares of the registrant's common stock, par value \$.01 per share, were outstanding.

The registrant's proxy or information statement relating to its Annual Meeting of Stockholders to be filed within 120 days of its June 30, 2005 fiscal year end is incorporated by reference into Part III of this Annual Report on Form 10-K.

PALATIN TECHNOLOGIES, INC.
TABLE OF CONTENTS

PART I

Page

| | | |
|---------|---|----|
| Item 1. | Business | 2 |
| Item 2. | Properties | 9 |
| Item 3. | Legal Proceedings | 9 |
| Item 4 | Submission of Matters to a Vote of Security Holders | 10 |

PART II

| | | |
|----------|--|----|
| Item 5. | Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities | 11 |
| Item 6. | Selected Consolidated Financial Data | 14 |
| Item 7. | Management's Discussion and Analysis of Financial Condition and Results of Operations | 15 |
| Item 7A. | Quantitative and Qualitative Disclosures About Market Risk | 27 |
| Item 8. | Financial Statements and Supplementary Data | 28 |
| Item 9. | Changes In and Disagreements With Accountants on Accounting and Financial Disclosure | 47 |
| Item 9A. | Controls and Procedures | 47 |
| Item 9B. | Other Information | 48 |

PART III

| | | |
|----------|--|----|
| Item 10. | Directors and Executive Officers of the Registrant | 49 |
| Item 11. | Executive Compensation | 49 |
| Item 12. | Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters | 49 |
| Item 13. | Certain Relationships and Related Transactions | 49 |
| Item 14. | Principal Accountant Fees and Services | 49 |

PART IV

| | | |
|----------|--|----|
| Item 15. | Exhibits and Financial Statement Schedules | 50 |
|----------|--|----|

[SIGNATURES](#)

[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 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 the 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 “Factors Affecting Our Business Condition” and elsewhere in this annual report, as well as in our other Securities and Exchange Commission (“SEC”) filings.

Overview

We are primarily focused on discovering and developing melanocortin (“MC”)-based therapeutics, which we believe is one of the fastest growing areas of pharmaceutical research and development. The MC family of receptors has been identified with a variety of conditions and diseases, including sexual dysfunction, obesity, cachexia (extreme wasting, generally secondary to a chronic disease), and inflammation. Our objective is to become a worldwide leader in MC-based therapeutics by pursuing a strategy based on commercializing our products under development and identifying new product targets through the utilization of our patented drug discovery platform.

In July 2004, we received approval from the U.S. Food and Drug Administration (“FDA”) to market NeuroSpec™, our proprietary radiolabeled monoclonal antibody product, for imaging and diagnosing equivocal

appendicitis. NeutroSpec is marketed and distributed by our strategic collaboration partner, Mallinckrodt Imaging, a business unit of Tyco Healthcare (“Mallinckrodt”). We are currently conducting additional clinical trials with NeutroSpec and evaluating its market potential as an imaging agent for osteomyelitis (infection deep inside a bone), fever of unknown origin, post-surgical infection and inflammatory bowel disease.

In August 2004, we entered into a collaborative development and marketing agreement with King Pharmaceuticals, Inc. (“King”), a specialty pharmaceutical company, to jointly develop and commercialize PT-141, a nasally administered peptide that is in clinical development for the treatment of both male and female sexual dysfunction. Pursuant to the terms of the agreement, Palatin and King will share all collaboration development and marketing costs and all collaboration net profits derived from net sales of PT-141 in North America based on an agreed percentage. Palatin and King currently plan to seek a partner for PT-141 for territories outside of North America and will jointly share in collaboration development and marketing costs and all collaboration revenues generated from those territories. We have the option to create, with King, a urology specialty sales force to co-promote the product in the U.S. if the product is successfully developed and commercialized.

In addition, we have preclinical development programs based on the MC family of receptors for various therapeutic indications including obesity and cachexia, and a program for congestive heart failure.

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 our product candidates under investigation; expansion of our pipeline through the utilization of our MC expertise and patented drug discovery platform; and opportunistic acquisition of synergistic products and technologies and partial funding of our development and discovery programs with the cash flow from our NeutroSpec and PT-141 collaboration agreements.

[Table of Contents](#)

We incorporated in Delaware in 1986 and commenced operations in the biopharmaceutical area in 1996. Our executive offices and research 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 Securities and Exchange Commission. 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

We are concentrating our efforts on the following products and development programs:

PT-141. PT-141, our lead therapeutic drug candidate, is a patented, nasally administered peptide that is in clinical development for the treatment of both male and female sexual dysfunction. PT-141 is a synthetic analog of the naturally occurring hormone alpha-MSH (melanocyte-stimulating hormone). It is an MC receptor-based therapeutic. The MSH class of hormones are potent regulators of a variety of physiological and behavioral functions, including the natural physiological sexual response. Our research suggests that PT-141 works through activation of MC receptors in the central nervous system rather than acting directly on the vascular system, which is a different mechanism of action from currently marketed male Erectile Dysfunction (“ED”) therapies. As a result, it may offer significant safety and therapeutic benefits over currently marketed products.

We have completed various Phase 1 safety studies and Phase 2A and Phase 2B efficacy studies in male subjects and patients. We have completed a Phase 1 safety study in female subjects and a Phase 2A efficacy study in female patients with Female Sexual Dysfunction (“FSD”).

We have initiated patient enrollment in two double-blind, placebo-controlled Phase 2B clinical trials of PT-141 in patients with ED. The main objectives of these studies are to further evaluate safety, treatment duration, patient populations and range of doses that will be incorporated into Phase 3 pivotal trials.

The first Phase 2B clinical trial will evaluate the safety and efficacy of PT-141 in 560 non-diabetic patients suffering from mild to severe ED. The second clinical trial will similarly evaluate 265 diabetic patients with ED. Both clinical trials will involve an “at home” three-month treatment period conducted at approximately 35 clinical trial sites throughout the United States. Additionally, the clinical trials will evaluate a range of PT-141 intranasal doses between 5 mg and 15 mg.

The non-diabetic Phase 2B clinical trial is scheduled to conclude in mid-calendar 2006, while the conclusion of the diabetic Phase 2B clinical is scheduled to follow in the second half of calendar 2006.

In addition, a Phase 2B at-home study of PT-141 in female patients with FSD is planned for later this calendar year.

Collaborative Development and Marketing Agreement with King. In August 2004, we entered into a collaboration agreement with King to jointly develop and commercialize PT-141. Pursuant to the terms of the agreement, we will share all collaboration development and marketing costs and all collaboration net profits derived from net sales of PT-141 in North America based on an agreed percentage. Palatin and King currently plan to seek a partner for PT-141 for territories outside of North America and will jointly share in collaboration development and marketing costs and all collaboration revenues generated from those territories. However, there can be no assurance that we will be able to enter into any such alliance or arrangement on terms acceptable to us or at all.

King paid us \$20.0 million at closing and may pay potential milestone payments to Palatin totaling up to \$100.0 million for achieving certain ED and FSD development and regulatory approval targets. After regulatory approval and commercialization of PT-141, King may also pay milestone payments to us totaling up to an additional \$130.0 million upon achieving specified annual North American net sales thresholds. A portion of the above milestones may be received in the form of equity purchases.

ED is defined as 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

[Table of Contents](#)

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 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 greater 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.

NeutroSpec™. NeutroSpec includes a radioactive technetium-labeled anti-CD 15 monoclonal antibody which selectively binds to a type of white blood cell, neutrophils, involved in the immune response. When injected into the blood stream, NeutroSpec binds to neutrophils accumulated at the infection site, labeling these cells with a radioactive tracer. As a result, physicians can rapidly image and locate an infection using a gamma camera, a common piece of hospital equipment that detects radioactivity. NeutroSpec offers the advantage of direct injection

and in vivo labeling of white blood cells, leading to a rapid and highly specific functional image of an infection in less than an hour, whereas the current standard of care, ex vivo radiolabeled white blood cells, requires a blood sample to be taken from the patient, processed by a nuclear pharmacy and then re-injected into the patient, with diagnostic images usually not available until 12-24 hours later.

In July 2004, we announced that we received full approval from the FDA to market NeutroSpec, for imaging of patients with equivocal signs and symptoms of appendicitis who are five years of age or older. NeutroSpec is marketed and distributed by our strategic collaboration partner, Mallinckrodt.

We are currently conducting additional clinical trials with NeutroSpec and evaluating its market potential as an imaging agent for osteomyelitis (infection deep inside a bone), fever of unknown origin, post-surgical infection and inflammatory bowel disease.

Strategic Collaboration Agreement with Mallinckrodt. On May 13, 2002, we entered into an agreement with Mallinckrodt to amend our Strategic Collaboration Agreement dated as of August 17, 1999. Under the terms of the original agreement, in addition to other provisions, Mallinckrodt paid us a licensing fee of \$500,000 and an additional \$13.0 million to purchase 700,000 restricted, unregistered shares of our preferred stock. Mallinckrodt agreed to pay us milestone payments of an additional \$10.0 million on FDA approval of the first NeutroSpec indication and on attainment of certain sales goals following product launch. We agreed to be responsible for the manufacture of NeutroSpec and Mallinckrodt agreed to pay us a transfer price on each product unit transferred to Mallinckrodt and a royalty on the net sales of NeutroSpec.

Under the terms of the amended agreement, Mallinckrodt committed up to an additional \$3.2 million, subject to certain conditions and attaining certain milestones, to offset a portion of the estimated expenses associated with completing the FDA review process. Additionally, timing of the original \$10.0 million in milestone payments was revised to coincide with NeutroSpec's FDA approval and achievement of future sales goals. The \$3.2 million has been paid in full and we received \$2.0 million upon FDA approval.

In June 2005, we extended our marketing agreement with Mallinckrodt to include exclusive marketing and distribution rights in Europe. The original agreement granted Mallinckrodt an exclusive license to market and distribute NeutroSpec worldwide, excluding Europe. Under the terms of the amendment, Palatin and Mallinckrodt will jointly develop and commercialize NeutroSpec for all global markets. Palatin and Mallinckrodt have developed an international regulatory strategy and expect to commence filings later this calendar year.

Each year, more than 250,000 Americans are diagnosed with acute appendicitis, an infection of the appendix. A timely and accurate diagnosis of this infection is crucial to ensure timely treatment and to prevent complications for the patient. A delay can entail hospital observation, outpatient treatment or surgery and can lead to increased risk of peritonitis, sepsis and other complications. Conversely, a misdiagnosed patient may experience unneeded hospital observation or unneeded surgery, which is expensive, inconvenient and utilizes limited resources. Every year, more than 350,000 patients present with equivocal appendicitis — this is when a specific diagnosis is uncertain and further testing is needed. In this situation, it is not always clear if the patient has appendicitis or another medical problem; nor is it exactly clear where the site of infection is located.

[Table of Contents](#)

We believe that NeutroSpec may improve patient diagnosis for appendicitis and that it has the potential to improve diagnosis of other acute and chronic infections, such as osteomyelitis, fever of unknown origin, post-surgical abscess, inflammatory bowel disease and pulmonary imaging. Approximately 700,000 patients are diagnosed with NeutroSpec's target indications each year.

MIDAS™ (Metal Ion-induced Distinctive Array of Structures). MIDAS is a proprietary platform technology that allows us to design and synthesize novel pharmaceuticals that mimic the activity of peptides, but which we believe offer significant advantages to conventional protein or peptide-based drugs. 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. Moreover, unlike most other drug discovery approaches, we believe that MIDAS is unique in that it can be used to generate either receptor antagonists (drugs that block a particular metabolic response) or agonists (drugs that promote a particular metabolic response). 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.

We have initiated a MIDAS program to discover and develop compounds that interact with the MC family of receptors. MC receptors regulate a diverse array of functions such as pigmentation, adrenocortical function, immune modulation, sexual arousal and energy maintenance. Based on this effort, we have preclinical development programs based on the MC family of receptors for various therapeutic indications including obesity and cachexia, and a program for congestive heart failure.

We have identified a series of lead compounds that decrease food intake and body weight in normal and genetically-obese animals. In January 2005, we presented data on our lead series of MC receptor, small molecule agonists, under development for the treatment of obesity, at the 2005 Keystone Symposia on Obesity: Molecular Physiology and Genetics of the Control of Body Weight.

The research, presented in a poster entitled "Regulation of Body Weight in Diet-Induced Obese Mice by A Small Molecule Melanocortin-4 Receptor Agonist," involved peripheral administration of one of our MC4 receptor-selective agonists to mice that became obese after being raised on a high-fat diet for several weeks. Administration of the MC4 receptor-selective agonist on a daily basis resulted in a 12% reduction in body weight by 10 days. This decrease in body weight was associated with a reduction in body fat, as well as decreased levels of blood glucose and plasma insulin. In addition to its effects in diet-induced obese animals, the MC4 receptor-selective agonist also was effective at reducing the body weight of genetically obese mice that are deficient in leptin, a protein involved in the regulation of food intake and energy expenditure.

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. We intend to seek to enter into strategic alliances or collaborative arrangements to provide additional financial and technical resources for MIDAS development.

Research and Development. Our current research and development efforts primarily focus on melanocortin-based therapeutics. We believe our technologies will facilitate the development of a portfolio of potential products. Over the last three fiscal years, we have spent the following amounts on company-sponsored research and development activities:

- year ended June 30, 2005: \$25.0 million
- year ended June 30, 2004: \$23.3 million
- year ended June 30, 2003: \$17.4 million

[Table of Contents](#)

Competition

Our products under development will compete on the basis of quality, performance, cost effectiveness, and application suitability with numerous established products and technologies. Products using new technologies which may be competitive with our proposed products may also be introduced by others. Many of the companies selling or developing competitive products have financial, manufacturing and distribution resources significantly greater than ours and may represent significant competition for us.

The pharmaceutical and biotechnology industry is characterized by extensive research efforts and rapid

technological change and there are 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 several FDA-approved drugs for ED in the United States and in certain foreign markets.

We are aware of several products under clinical development for both ED and FSD. We cannot assure you that our competitors will not succeed in the future 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 applications, if any, for which our products receive approval, and the effectiveness, cost, safety and ease of use of our products in comparison to the products of our competitors.

We are aware of one company marketing an antibody-based product which may compete with NeutroSpec for certain indications. The competing product is marketed in some European countries. We are also aware of at least one other company developing a peptide-based product which may also compete with NeutroSpec for certain indications. In addition, other technologies are also used to diagnose appendicitis, including computerized tomography or CT scan, and ultrasound technologies.

We have many competitors, including pharmaceutical and biotechnology companies. Many of these competitors have substantially greater capital and other resources than we do. Furthermore, there are several well-established products in our target markets that we will have to compete against. 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.

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, selectively, in those foreign countries where protection is important to the development of our business.

We have exclusive rights to patents and applications relating to certain compounds and methods of treatment for sexual dysfunction, and own two issued United States patents and pending United States and foreign applications covering PT-141. The claims of issued patents covering PT-141 may not provide meaningful protection. In addition, third parties may challenge the validity or scope of any issued patent.

We own patents covering certain aspects of NeutroSpec, but the claims of those patents may not be effective in preventing others from developing competing products. In addition, the validity of these patents has not been determined.

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.

[Table of Contents](#)

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.

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 PT-141 or NeutroSpec or by our methods of making PT-141 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 money 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.

Government rights. Some patents we license or own cover inventions partially developed with funds from United States government agencies. As a result of these arrangements, the United States government may have rights to certain inventions developed during the course of the performance of federally funded projects, as required by law or agreements with the funding agency. In addition, we may be required to manufacture in the United States products to be sold in the United States.

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 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 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. The FDA has required specific post-marketing studies for NeutroSpec, including additional clinical studies with pediatric patients and patients with specified conditions, and additional assay development and validation. These post-marketing studies must be completed by various deadlines, primarily over the next two years.

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

[Table of Contents](#)

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 NeuroSpec and PT-141. We currently have agreements in place for the commercial manufacture of NeuroSpec. We anticipate that collaborators, licensees or contract manufacturers will also manufacture PT-141 and proposed products resulting from MIDAS technology.

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 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. 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, health care 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 in commercial quantities under cGMPs. We intend to rely on collaborators, licensees or contract manufacturers for the commercial manufacture of our proposed products.

We are dependent on DSM N.V. of the Netherlands for the manufacture of the NeuroSpec drug substance and intermediate drug product and on Ben Venue Laboratories of Cleveland, Ohio for the manufacture of the final NeuroSpec drug product. The failure of either of these manufacturers to comply with FDA cGMPs or to supply these key components of NeuroSpec, 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.

Our PT-141 product and certain proposed products resulting from our MIDAS technology are synthetic peptides. The peptides are synthesized from commercially-available amino acids, and the production process involves well-established technology. We currently contract with third-party manufacturers for the production of peptides and anticipate doing so in the future.

We rely on our arrangement with Mallinckrodt to market, sell and distribute NeuroSpec. We have limited control over these activities. If PT-141 is successfully developed and approved for marketing, we will be highly dependent on King, our strategic collaboration partner, for certain marketing and sales 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.

[Table of Contents](#)**Product Liability and Insurance**

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

Employees

As of September 1, 2005, we employed 81 persons full time, of whom 66 are engaged in research and development activities and 15 are engaged in administration and management. Twenty-three of our employees hold Ph.D. degrees. We have been successful in attracting skilled and experienced scientific personnel, however, 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 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.

Item 2. Properties.

Our corporate offices and research and development facility 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 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.

In June 2005, the Company settled an arbitration demand filed by Competitive Technologies, Inc. ("CTI"), seeking arbitration before the American Arbitration Association on issues relating to a license agreement with CTI. Under the license agreement, the Company exclusively licenses for a defined field certain compounds and methods developed at the University of Arizona. The arbitration demand concerned the amount CTI was to receive as a result of payments by King to the Company under the collaboration agreement. CTI demanded \$4.0 million in the arbitration. Prior to the arbitration demand the Company had offered to pay CTI \$1.0 million. In settlement, the Company agreed to pay CTI \$1.7 million in cash and issue to CTI 170,000 shares of the Company's common stock. CTI agreed to withdraw its demand for arbitration with prejudice and to release the Company from liability for any claims for amounts due under the license agreement that are based on the collaboration agreement between the Company and King. The Company and King exclusively retain all rights to PT-141.

There are no other material legal proceedings pending against us.

[Table of Contents](#)**Item 4. Submission of Matters to a Vote of Security Holders.**

At a special meeting of stockholders on June 9, 2005, the stockholders approved the adoption of the

Company's 2005 Stock Plan, which authorizes the grant of up to 5,000,000 shares of common stock under stock options or certain other stock-based awards.

Common stock and Series A convertible preferred stock voted as a single class on all matters. The following table shows the votes cast.

| | <u>For</u> | <u>Against</u> | <u>Abstentions</u> |
|-----------------------------|------------|----------------|--------------------|
| Approval of 2005 Stock Plan | 17,679,191 | 9,505,344 | 472,954 |

Abstentions were counted neither for nor against the proposal.

[Table of Contents](#)

PART II

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

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

The table below provides, for the fiscal quarters indicated, the reported high and low sales prices for the common stock on AMEX since July 1, 2003.

| | | |
|---------------------------------|--------|--------|
| FISCAL YEAR ENDED JUNE 30, 2005 | HIGH | LOW |
| Fourth Quarter | \$2.24 | \$1.70 |
| Third Quarter | \$2.57 | \$2.03 |
| Second Quarter | \$2.97 | \$2.35 |
| First Quarter | \$4.25 | \$2.52 |
| FISCAL YEAR ENDED JUNE 30, 2004 | HIGH | LOW |
| Fourth Quarter | \$4.49 | \$3.35 |
| Third Quarter | \$4.24 | \$2.55 |
| Second Quarter | \$5.89 | \$2.19 |
| First Quarter | \$5.25 | \$2.66 |

Holder of common stock. On September 1, 2005, we had approximately 270 holders of record of common stock. On September 1, 2005 the closing sales price of our common stock as reported on the AMEX was \$2.10 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 11,347 shares on September 1, 2005, 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.

[Table of Contents](#)

**EQUITY COMPENSATION PLAN INFORMATION
AS OF JUNE 30, 2005**

| Plan category | Number of securities to be issued upon exercise of outstanding options, warrants and rights (1) | Weighted-average exercise price of outstanding options, warrants and rights | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
|--|---|---|---|
| | (a) | (b) | (c) |
| Equity compensation plans approved by security holders (2) | 5,078,254 | \$3.31 | 4,984,793 |
| Equity compensation plans not approved by security holders | 1,511,062 | \$3.16 | 0 |
| Total | 6,589,316 | | 4,984,793 |

- (1) Does not include a total of 19 shares of aggregate fractions. No fractional shares will be issued on exercise of options or warrants.
- (2) Includes individual option and warrant agreements we assumed when we merged with RhoMed Incorporated in 1996. Options and warrants to purchase 457,515 shares of common stock are outstanding under the assumed agreements, with a weighted average exercise price of \$2.50 per share. No additional options or warrants are available for issuance under the assumed agreements, except that the number of shares purchasable under certain warrants may increase due to anti-dilution provisions.

We have authorized the issuance of equity securities under the compensation plans described below, without the approval of stockholders. No additional options, warrants or rights are available for issuance under any of these plans, except for additional shares which may become purchasable under warrants with anti-dilution protection as noted below. We have already registered for resale the common stock underlying all of these options and warrants.

- 1997 Executive Officers Stock Option Agreement, dated June 3, 1997: provided common stock purchase options to three executive officers. Options to purchase 26,766 shares at \$4.96 per share remain outstanding with an expiration date of June 3, 2007.
- Richard J. Murphy Stock Option Agreement, dated December 4, 1997: provided common stock purchase 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.
- Cedar Brook II Corporate Center, L.P. warrants, dated April 6, 2001 and December 17, 2001: provided common stock purchase warrants to the lessor of our office and laboratory facility to purchase 30,000 shares at \$2.90 per share, with an expiration date of April 6, 2006, and 25,000 shares at \$3.65 per share with an expiration date of December 17, 2006.

- 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.

[Table of Contents](#)

- 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 1,318,230 shares. These warrants have the following share amounts, prices (rounded to the nearest cent) and expiration dates:

| <u>Offering</u> | <u>Shares Purchasable</u> | <u>Exercise Price</u> | <u>Expiration Date</u> |
|-----------------|---------------------------|-----------------------|------------------------|
| Fall 2000 | 216,000 | \$6.60 | 10-05-05 |
| Fall 2000 | 87,884 | \$6.53 | 10-27-05 |
| Fall 2001 | 134,188 | \$2.66 | 10-29-06 |
| Fall 2001 | 221,872 | \$2.70 | 10-29-06 |
| June 2002 | 109,510 | \$2.75 | 06-13-07 |
| July 2002 | 51,502 | \$1.46 | 07-29-07 |
| July 2002 | 38,627 | \$1.37 | 07-29-07 |
| Fall 2002 | 458,647 | \$1.54 | 11-15-07 |

[Table of Contents](#)

Item 6. Selected Consolidated 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 the “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,

| | 2005 (2) | 2004 | 2003 | 2002 | 2001 | |
|--------------------------------|----------|--------|--------|--------|--------|--------|
| Statement of Operations Data: | | | | | | |
| REVENUES | | | | | | |
| Royalties | \$ 1,586 | \$ - | \$ - | \$ - | \$ - | |
| Product sales | 2,474 | - | - | - | - | |
| Licenses, grants and contracts | | 13,897 | 2,315 | 1,270 | 281 | 1,788 |
| Total revenues | 17,957 | 2,315 | 1,270 | 281 | 1,788 | |
| OPERATING EXPENSES | | | | | | |
| Cost of product sales | 535 | - | - | - | - | |
| Royalties | 328 | - | - | - | - | |
| Research and development | | 25,045 | 23,333 | 17,439 | 12,117 | 10,109 |
| General and administrative | | 7,461 | 5,740 | 4,867 | 5,004 | 3,025 |

| Total operating expenses | 33,369 | 29,073 | 22,306 | 17,121 | 13,134 |
|--|-------------|-------------|-------------|-------------|-------------|
| OTHER INCOME (EXPENSE) | | | | | |
| Investment income | 488 | 222 | 248 | 312 | 788 |
| Interest expense | (14) | (23) | (22) | (3) | (5) |
| Total other income, net | 474 | 199 | 226 | 309 | 783 |
| Loss before income taxes and cumulative effect of accounting change | (14,938) | (26,559) | (20,810) | (16,531) | (10,563) |
| Income tax benefit | 580 | 241 | 245 | 392 | 325 |
| Loss before cumulative effect of accounting change | (14,358) | (26,318) | (20,565) | (16,139) | (10,238) |
| Cumulative effect of accounting change (1) | -- | -- | -- | -- | (361) |
| NET LOSS | (14,358) | (26,318) | (20,565) | (16,139) | (10,599) |
| DEEMED DIVIDEND | - | -- | (203) | (297) | -- |
| NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS | \$ (14,358) | \$ (26,318) | \$ (20,768) | \$ (16,436) | \$ (10,599) |
| Basic and diluted net loss attributable to common stockholders before cumulative effect of accounting change | | | | | |
| | \$ (0.27) | \$ (0.55) | \$ (0.73) | \$ (1.16) | \$ (1.01) |
| Cumulative effect of accounting change (1) | | | | | |
| | - | -- | -- | -- | (0.04) |
| Basic and diluted net loss attributable to common stockholders per common share | | | | | |
| | \$ (0.27) | \$ (0.55) | \$ (0.73) | \$ (1.16) | \$ (1.05) |
| Weighted average common shares outstanding | | | | | |
| | 53,861 | 47,688 | 28,362 | 14,195 | 10,131 |

Balance Sheet Data (at period end): (3)

| | | | | | |
|--|-----------|-----------|-----------|----------|-----------|
| Cash, cash equivalents and investments | \$ 18,106 | \$ 20,412 | \$ 18,383 | \$ 9,105 | \$ 11,456 |
| Property and equipment, net | 6,464 | 6,356 | 7,246 | 2,416 | 1,925 |
| Working capital | 13,772 | 15,485 | 14,742 | 5,783 | 9,360 |
| Total assets | 35,166 | 27,800 | 26,568 | 12,358 | 14,244 |
| Long term debt, net of current portion | 19 | 30 | 76 | -- | -- |
| Stockholders' equity | 9,225 | 19,387 | 18,657 | 8,687 | 11,916 |

- (1) In the fiscal year ended June 30, 2001, we recorded a non-cash charge for the cumulative effect related to the adoption of SEC Staff Accounting Bulletin No. 101. See Note 2 to the Consolidated Financial Statements.
- (2) In the fiscal year ended June 30, 2005, we received FDA approval to market NeutroSpec for equivocal appendicitis.
- (3) In the fiscal year ended June 30, 2005, we reclassified as assets certain tenant construction allowances provided by the lessor of our office space in the fiscal year ended June 30, 2003. Prior period amounts have been reclassified accordingly.

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

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 over the related performance period. Due to the uncertainty inherent in its development programs, including the possibility that a program is terminated prior to completion without a payment obligation on the part of the Company, the Company recognizes such revenue on a straight-line basis, as it believes that no other basis is more reflective of the pattern over which such revenue is earned. We consider our performance period under the King collaboration to be the period in which we perform development activities during initial research term, which is currently estimated to be five years from the inception of the agreement. Specific performance periods are not stated in the agreement and are 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 its estimated performance period accordingly. The actual performance period may vary based on the results of the related development activities, changes in development plans agreed by the parties, regulatory requirements and other factors. Increases in the estimated performance period would 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. In the fourth quarter of the fiscal year ended June 30, 2005, the Company increased its estimate for its period of performance under the King collaboration and, accordingly, reduced the amount of deferred revenue recognized during the quarter by approximately \$235,000 compared to the previous quarter.

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 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 method, which requires us to make estimates of future interest rates, 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 or pro forma disclosure related to an option grant is not adjusted for subsequent changes in these estimates or for actual experience.

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. As a result, stock-based compensation charges may vary significantly from period to period.

Results of Operations

Year Ended June 30, 2005 Compared to the Year Ended June 30, 2004:

Royalties and product sales – For the year ended June 30, 2005, we recognized product sales of \$2.5 million and royalty revenues of \$1.6 million, related to NeutroSpec, from Mallinckrodt pursuant to our collaboration agreement. The Company received FDA approval to market NeutroSpec in July 2004. Accordingly, there was no product revenue or royalty revenue recognized for the year ended June 30, 2004. In the three month periods ended June 30, 2005, March 31, 2005, December 31, 2004 and September 30, 2004, we recognized \$0.6 million,

[Table of Contents](#)

million, \$0.2 million and \$0.3 million, respectively, of royalties from Mallinckrodt, based on their net sales to customers. In the three month periods ended June 30, 2005, March 31, 2005, December 31, 2004 and September 30, 2004, we recognized \$0.8 million, \$0, \$1.3 million and \$0.4 million, respectively, of product sales to Mallinckrodt. Each Mallinckrodt purchase from the Company is subject to certain minimum quantities, resulting in a limited number of product shipments by the Company during the year. Product sales are billed upon shipment of product to Mallinckrodt on standard trade terms. Revenue is recognized upon acceptance of the product by Mallinckrodt based on conformance with product specifications. Accordingly, the Company's periodic revenue from product sales is highly dependent on the timing of orders and shipments.

Licenses, grants and contracts – For the year ended June 30, 2005, we recognized \$13.9 million of revenue from licenses, grants and contracts compared to \$2.3 million for the year ended June 30, 2004. In the fiscal year ended June 30, 2005, we recognized \$11.5 million of revenue related to our collaboration agreement with King related to PT-141, which commenced in August 2004. The revenue consisted of \$8.1 million of reimbursements for King's share of PT-141 development expenses and \$3.4 million of license fees, which represents the portion of King's August 2004 up-front payment recognized as revenue during the year. There was no revenue from King during the fiscal year ended June 30, 2004. In the fiscal year ended June 30, 2005, we recognized approximately \$2.4 million of revenue under collaboration agreements with Mallinckrodt for the development of NeutroSpec compared with \$2.2 million in the fiscal year ended June 30, 2004. Revenue in the current fiscal year included a \$2.0 million milestone payment upon obtaining FDA approval for equivocal appendicitis and \$0.4 million of reimbursements for Mallinckrodt's share of development expenses for other indications of NeutroSpec. Revenue in the fiscal year ended June 30, 2004 consisted of a \$2.0 million milestone payment and \$0.2 million of deferred license fee revenue from up-front payments received in 1999 and 2002. In addition, in the fiscal year ended June 30, 2004, the Company recognized approximately \$0.1 million in grant revenue from the Department of Health and Human Services. The Company expects to continue to earn contract revenue from King and Mallinckrodt as the development of PT-141 and NeutroSpec continues, in the form of reimbursement of shared development costs and the recognition of deferred license fees. The Company may also earn contract revenue from Mallinckrodt and King based on the attainment of certain development milestones.

Cost of product sales and royalties – For the fiscal year ended June 30, 2005, we recognized \$0.5 million and \$0.3 million, respectively, in cost of product sales and royalties related to NeutroSpec, which was approved by the FDA in July 2004. There was no corresponding cost of product sales or royalties for the fiscal year ended June 30, 2004. 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 use and sell this inventory, the cost of product sales we recognize will exclude amounts previously expensed. On the date of approval, the Company had sufficient active drug substance to produce all of the product units sold to date. Cost of sales for these units includes primarily packaging and other materials. We expect our cost of product revenue to increase significantly in future periods as this inventory is consumed and replaced.

Research and development – Research and development expenses increased to \$25.0 million for the year ended June 30, 2005 compared to \$23.3 million for the year ended June 30, 2004. In the fiscal year ended June 30, 2005, development spending directly associated with PT-141 increased approximately \$4.4 million, as costs related to processing drug product, including manufacturing, analytical and process development and equipment costs were partially offset by lower spending on clinical studies. Increased spending on the development of PT-141 was largely offset by a \$4.2 million decrease in spending on NeutroSpec development. The fiscal year ended June 30, 2004 included greater nonclinical spending on NeutroSpec, prior to FDA approval in July 2004, primarily related to processes for the manufacturing of drug product. In the fiscal year ended June 30, 2005, development expenses of the MIDAS program were comparable to the prior year. Indirect research and development costs, including personnel costs and certain license fees, increased \$1.5 million in the fiscal year ended June 30, 2005.

General and administrative – General and administrative expenses increased to \$7.5 million for the year ended June 30, 2005 compared to \$5.7 million for the year ended June 30, 2004. Personnel, consulting, legal and insurance expenses increased, reflecting the general expansion of the Company's business activities, its licensing activities, the July 2004 approval of NeutroSpec and additional accounting and regulatory requirements.

Investment income – Investment income increased to \$0.5 million for the year ended June 30, 2005 from \$0.2 million for the year ended June 30, 2004, primarily reflecting income on greater invested cash balances maintained during the period, which was partially offset by recognized losses on securities.

[Table of Contents](#)

Income tax benefit — During the fiscal years ended June 30, 2005 and 2004, the Company sold New Jersey state net operating loss carryforwards and research and development credits, which resulted in the recognition of \$0.6 million and \$0.2 million of income tax benefits, respectively. Assuming the state of New Jersey continues to fund this program, which is uncertain, 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, 2004 Compared to the Year Ended June 30, 2003

Licenses, grants and contracts – For the year ended June 30, 2004, revenue from licenses, grants and contracts increased to \$2.3 million from \$1.3 million in the fiscal year ended June 30, 2003. In the fiscal year ended June 30, 2004, we recognized \$2.2 million in revenue related to NeutroSpec pursuant to our collaboration agreement with Mallinckrodt, including a \$2.0 million milestone payment and \$0.2 million of deferred license revenue on up-front payments received from Mallinckrodt in 1999 and 2002. In the fiscal year ended June 30, 2003, under agreements with Mallinckrodt related to NeutroSpec, we recognized \$0.4 million of milestone payments, \$0.6 million of revenue deferred from the 1999 and 2002 payments, and \$0.1 million of reimbursements for certain development costs. In addition, in each of the fiscal years ended June 30, 2004 and 2003, we recorded \$0.1 million in grant revenue pursuant to the Small Business Technology Transfer programs of the Department of Health and Human Services.

Research and development – Research and development expenses increased to \$23.3 million for the fiscal year ended June 30, 2004 compared to \$17.4 million for the fiscal year ended June 30, 2003. The increase in R&D was primarily related to increased development efforts and clinical trials of PT-141 and NeutroSpec, for which direct spending increased approximately \$2.0 million and \$2.4 million, respectively, primarily related to manufacturing and process development. Indirect development expenses, including personnel, increased approximately \$1.4 million while spending on MIDAS increased approximately \$0.1 million.

General and administrative – General and administrative expenses increased to \$5.7 million for the fiscal year ended June 30, 2004 compared to \$4.9 million for the fiscal year ended June 30, 2003. The increase in general and administrative expenses is primarily attributable to the increases in marketing and business development expenses, salaries and other stock-based compensation and related personnel expenses.

Income tax benefit — During the fiscal years ended June 30, 2004 and 2003, the Company sold New Jersey state net operating loss carryforwards and research and development credits, which resulted in the recognition of \$0.2 million of income tax benefits, in each year. Assuming the state of New Jersey continues to fund this program, which is uncertain, the actual amount of net operating losses and tax credits we may sell will also depend upon the allocation among qualifying companies of an annual pool established by the state of New Jersey.

Deemed dividend — Based on the sales price of common stock sold in private placements, the exercise prices of certain outstanding warrants were adjusted downward in accordance with their existing terms. As a result, a deemed dividend of \$0.2 million was reflected in the Company's consolidated statement of operations for the fiscal year ended June 30, 2003. There was no deemed dividend reflected in the Company's consolidated statement of operations for the fiscal year ended June 30, 2004 since there was no downward adjustment of the

exercise prices of certain outstanding warrants.

Liquidity and Capital Resources

Since inception, we have incurred net operating losses, primarily related to spending on our research and development programs. As of June 30, 2005, we had an accumulated deficit of \$131.5 million. We have financed our net operating losses primarily through equity financings and revenue received under collaborative agreements.

As of June 30, 2005, we had cash and cash equivalents of \$15.7 million and short-term investments of \$2.4 million.

Our product candidates are at various stages of research and development and some may never be successfully developed or commercialized. We received regulatory approval to market and sell NeuroSpec for diagnosis of appendicitis, and we will need regulatory approval to market and sell PT-141, MIDAS products and NeuroSpec for other indications. PT-141, MIDAS products and NeuroSpec for other indications will require significant further research, development and testing. We may experience uncertainties, delays, difficulties and

[Table of Contents](#)

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.

Failure to obtain timely regulatory approval for our other products and indications would impact our ability to increase sales 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.

In July 2004, we received approval from the FDA to market NeuroSpec. Approval of NeuroSpec does not assure the product's commercial success. If NeuroSpec does not achieve adequate market acceptance, our financial condition and results of operations will be adversely affected.

During the fiscal year ended June 30, 2005, we used \$5.1 million of cash for our operating activities compared to \$23.7 million in the fiscal year ended June 30, 2004. The decrease is primarily the result of cash received under our collaboration agreement with King, which was completed in August 2004. In the year ended June 30, 2005, our accounts receivable and inventory balances increased \$5.4 million and \$1.4 million, respectively. The Company's accounts receivable balance as of June 30, 2005 consists of trade receivables from its collaboration agreements. Accounts receivable from King amounted to \$4.0 million, representing King's share of development expenses incurred by the Company during the quarter ended June 30, 2005 and due after the end of the quarter, net of advances. Accounts receivable from Mallinckrodt amounted to \$1.4 million, representing royalty revenue recorded by the Company based on Mallinckrodt's net sales during the quarter ended June 30, 2005 and due from Mallinckrodt after the end of the quarter and amounts due on product sales in the fourth quarter.

During the fiscal year ended June 30, 2005, cash used in investing activities was \$0.9 million, primarily reflecting costs associated with the expansion of the Company's laboratory and office facilities. In the year ended June 30, 2004, the maturity of short-term investments provided \$1.2 million of cash from investing activities, net of \$0.2 million of property and equipment purchases.

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.

During the fiscal year ended June 30, 2005, net cash provided by financing activities was \$3.8 million, due primarily to proceeds from the issuance of common stock and warrants to King and the exercise of options and warrants. During the fiscal year ended June 30, 2004, net cash provided by financing activities was \$26.2 million, primarily from a private placement of common stock and warrants completed in January 2004, which resulted in net proceeds to the Company of approximately \$21.0 million. The exercise of options and warrants provided another \$5.4 million in the fiscal year ended June 30, 2004.

In the January 2004 private placement, investors, consisting of domestic financial institutions and other accredited investors, purchased 7.0 million shares of common stock and 1.0 million warrants, which equates to 15% warrant coverage on the number of shares they purchased, at an offering price of \$3.25 per share. Each warrant entitles the purchaser to purchase one share of common stock at an exercise price of \$4.06 per share. The net proceeds were \$21.0 million, which continue to be used primarily for general corporate purposes, especially for the development and clinical trials of new products based on our proprietary technologies.

In November 2002 and March 2003, we received aggregate gross proceeds of \$30.6 million in private placements of common stock and warrants. Investors, consisting of domestic and European financial institutions and other accredited investors, purchased 22.8 million shares of common stock: 9,373,940 shares at \$1.23 per share and

[Table of Contents](#)

13,433,096 shares at \$1.42 per share. For every five shares purchased in the November 2002 offering and for every four shares purchased in the March 2003 offering, the investors also received a five-year warrant to purchase one share of common stock at an exercise price of \$1.54 for the November 2002 offering and \$1.77 for the March 2003 offering. The net proceeds of \$28.8 million were used primarily for general corporate purposes, especially for the development and clinical trials of new products based on our proprietary technologies. In addition, in July 2002, we received gross proceeds of \$1.8 million pursuant to a private placement of common stock and warrants. Investors, consisting of domestic and European financial institutions and other accredited investors, purchased approximately 1.5 million shares of common stock shares at \$1.17 per share. For every five shares purchased, the investors also received a five-year warrant to purchase one share of common stock at an exercise price of \$1.46. The net proceeds of \$1.7 million were used primarily for general corporate purposes, especially for the development and clinical trials of new products based on our proprietary technologies.

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 expect that our existing capital resources will be adequate to fund our projected operations through at least June 30, 2006, based on current and projected expenditure levels, which include receiving certain milestone payments from collaborative partners. 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 intend to continually monitor the progress of our development programs and the timing and amount of related expenditures and potential milestone receipts and may seek additional financing during the fiscal year ending June 30, 2006. We plan to continue to refine our operations, control expenses, evaluate alternative methods to conduct our business and seek available and attractive sources of financing and sharing of development costs through strategic collaboration agreements or other resources.

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 and market such technologies and proposed products. The time required to reach profitability is highly uncertain, and

we do not know whether we will be able to achieve profitability on a sustained basis, if at all.

Contractual Obligations

As outlined in Note 8 of the Notes to our Consolidated Financial Statements, we have entered into various contractual obligations and commercial commitments. The following table summarizes our most significant contractual obligations as of June 30, 2005:

| | Payments due by Period | | | | |
|-------------------------------|------------------------|---------------------|-------------|-------------|---------------|
| | Total | Less than 1 Year | 1 - 3 Years | 4 - 5 Years | After 5 Years |
| Facility operating leases | \$13,146,597 | \$1,823,753 | \$4,459,180 | \$3,026,081 | \$3,837,583 |
| Capital lease obligations | 33,873 | 13,549 | 20,324 | - | - |
| License agreements (a) | 2,325,000 | 225,000 | 450,000 | 450,000 | 1,200,000 |
| | ----- | ----- | ----- | ----- | ----- |
| Total contractual obligations | \$15,505,470 | \$2,062,302 | \$4,929,504 | \$3,476,081 | \$5,037,583 |
| | ===== | ===== | ===== | ===== | ===== |

(a) The Company's license agreements also include royalty and other contingent payment obligations and may be terminated by the Company under certain conditions.

Factors Affecting our Business Condition

In addition to the other information included in this annual report on Form 10-K, the following risks should be considered in evaluating our business and future prospects:

[Table of Contents](#)

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

We have never been profitable and we may never become profitable. As of June 30, 2005, we had an accumulated deficit of \$131.5 million and a loss for the year then ended of \$14.4 million. Our only approved product is NeutroSpec for equivocal appendicitis. We expect to incur additional losses as we continue our development of NeutroSpec for other indications, PT-141 and MIDAS. Unless and until we receive approval from the FDA or other regulatory authorities for our other product candidates, we cannot sell our other 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 the sale of NeutroSpec, license and other contract revenue under our existing collaborative development agreements and from cash, cash equivalents and investments on hand. We will need to seek additional 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 discontinue product development, reduce or forego sales and marketing efforts 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.

We received FDA approval to market NeutroSpec in July 2004 and have not yet demonstrated our ability to perform the functions necessary for the continued success of the commercialization of NeutroSpec over time or for the successful commercialization of any of our other product candidates. 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;
- conducting sales and marketing activities; and
- obtaining additional capital.

Our operations to date have been primarily focused on organizing and staffing our Company, 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.

If NeuroSpec does not achieve market acceptance, our business will suffer.

Approval of NeuroSpec for marketing and sale does not assure the product's commercial success. NeuroSpec will compete with other diagnostic imaging modalities and drugs manufactured and marketed by major pharmaceutical and other biotechnology companies. Imaging agents such as NeuroSpec generally take longer to achieve market acceptance following marketing approval than many other drugs. The degree of market acceptance of NeuroSpec will depend on a number of factors, including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of NeuroSpec;
- cost-effectiveness of NeuroSpec relative to competing products and technologies;
- availability of reimbursement for our products from government or other healthcare payors;
- the establishment and demonstration of the clinical efficacy and safety; and
- potential advantage over alternative treatment methods.

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

Our revenues may fluctuate and we may fail to meet periodic projected sales levels.

We received FDA approval to market NeuroSpec in July 2004 and have limited experience on which to base our expectations of the timing and levels of future sales. In addition, our sales to Mallinckrodt are subject to certain minimum order quantities. As a result, our periodic revenue is highly dependent on the timing of orders and shipments and may vary significantly from period to period. Therefore, the amount our periodic product sales may

[Table of Contents](#)

not be an indication of future results. However, if our quarterly sales levels do not meet investor expectations, the price of our common stock could decline.

Development and commercialization of our proposed product and technologies involves a lengthy, complex and costly process and we may never develop or commercialize any other products other than NeuroSpec.

Our other product candidates are at various stages of research and development, will require regulatory approval, and may never be successfully developed or commercialized. PT-141 and MIDAS products will require significant further research, development and testing. You should evaluate us in light of the uncertainties, delays, difficulties and expenses commonly experienced by early stage biopharmaceutical companies, which may include unanticipated problems and additional costs relating to:

- the research, 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 and competition.

The regulatory approval process is lengthy, expensive and uncertain, and may prevent us from obtaining the approval 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 trial and formulation studies;
- submission to the FDA of an investigational new drug application, or 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;
- the submission of a new drug application, or NDA, to the FDA; and
- FDA review and approval of the NDA 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 a NDA. The NDA also must contain extensive manufacturing information. Once the submission has been accepted for filing, the FDA generally has 180 days 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 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 delay or prevent marketing of potential products for a considerable period of time and impose costly procedures upon our activities. Success in early stage clinical trials does not assure success

[Table of Contents](#)

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.

The FDA has required specific post-marketing studies for NeutroSpec, including additional clinical studies with pediatric patients and patients with specified conditions, and additional testing and development of assays. These post-marketing studies must be completed by various deadlines, primarily over the next two years.

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 review and periodic inspections by the FDA and other authorities where applicable, and must comply with ongoing regulatory requirements, including the FDA's current Good Manufacturing Practices ("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 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 rely on third parties to conduct clinical trials for our product candidates and their failure to timely perform their obligations could significantly harm our product development.

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

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 NeutroSpec and PT-141 depend on contract manufacturers over whom we have no control.

We do not have the facilities to manufacture NeutroSpec or PT-141. We depend on DSM N.V. of the Netherlands for the manufacture of the antibody used in NeutroSpec and on Ben Venue Laboratories of Cleveland, Ohio for the manufacture of NeutroSpec kits. For our development activities, we rely on other contract manufacturers for the manufacture of PT-141. 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 negatively impact our ability to receive continued FDA approval of NeutroSpec or receive FDA approval of our other potential products. The failure of these manufacturers to supply these key components of NeutroSpec, or their inability to comply with FDA manufacturing regulations, could force us to seek other manufacturers and could interfere with our ability to deliver product. Establishing relationships with new suppliers, any of whom 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 NeutroSpec, PT-141 and MIDAS could result in a liability exceeding our financial resources.

Our research and development of NeutroSpec, PT-141 and MIDAS 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 limited or no experience in marketing, distributing and selling products and will substantially rely on our marketing partners to provide these capabilities.

We depend on Mallinckrodt, our strategic collaboration partner, to market, sell and distribute NeutroSpec. If Mallinckrodt fails to market NeutroSpec or devote enough resources to NeutroSpec, our potential revenues from the sale of NeutroSpec 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. In addition, if the FDA approves PT-141 for marketing and sale, we will depend on our arrangements with King Pharmaceuticals for the marketing, distribution and sale of PT-141. If King fails to market PT-141 or devote enough resources to PT-141, our potential revenues from the sale of PT-141 will be adversely affected. If these arrangements fail, we may have difficulty establishing new marketing relationships, and in any event, we will have limited control over these activities.

Competing products and technologies may make NeutroSpec and our other potential products noncompetitive.

We are aware of one company marketing an antibody-based product which may compete with NeutroSpec for certain indications. The competing product is marketed in some European countries. We are also aware of at least one other company developing a peptide-based product which may also compete with NeutroSpec for certain indications. In addition, other technologies may also be used to diagnose appendicitis, including computerized tomography or CT scan, and ultrasound technologies.

We are aware of three oral FDA-approved drugs for the treatment of erectile dysfunction. These products are also approved in Europe, Japan and most of the world's pharmaceutical markets. In addition, we are aware of at

least two other products treating erectile dysfunction that have been submitted for approval in the United States, Europe and most of the world's pharmaceutical markets. In order to achieve approval and market acceptance, PT-141 may potentially be required to demonstrate efficacy and safety equivalent or superior to these other products.

The biopharmaceutical and diagnostic industries are highly competitive. We are likely to encounter significant competition with respect to NeutroSpec, PT-141 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 and less costly than NeutroSpec, PT-141 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 health care payers.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of health care costs to contain or reduce costs of health care 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 health care 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 health care in the U.S. and the concurrent growth of organizations such as HMOs could control or significantly influence the purchase of health care services and products. In addition, legislative proposals to reform health care 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 health care payers and providers are instituting and the effect of any health care 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 would 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 may be unable to make or market NeutroSpec, in which case we may lose the value of our substantial investment in developing the product, as well as any future revenues from selling NeutroSpec.

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

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

- the degree and range of protection any patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- if and when patents will be issued;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; and

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

[Table of Contents](#)

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

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

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

In addition to our reliance on patents, we attempt to protect our proprietary technologies and processes by relying on trade secret laws, nondisclosure and confidentiality agreements, and licensing arrangements 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 otherwise gain access to our trade secrets or technology, either of which could materially and adversely affect our competitive position.

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 party to various arrangements with academic, governmental and 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 have an agreement with Mallinckrodt under which they sell NeutroSpec. If Mallinckrodt were to become unwilling or unable to provide these services, we would have to quickly make alternative arrangements with third parties, which could adversely affect the commercialization of NeutroSpec.

We intend to continue 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.

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.

[Table of Contents](#)

We are highly dependent on our management team and senior research professionals.

As of September 1, 2005 we employed less than 100 people and 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. In addition, 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 the Company to additional risks, including the need to devote significant resources to new activities and to raise additional funds.

Trading in our stock over the last 12 months has been limited, so investors may not be able to sell as much stock as they want at prevailing prices.

The average daily trading volume in our common stock for the 12 month period ended September 1, 2005 was less than 900,000 shares. If limited trading in our stock continues, it may be difficult for investors to sell their shares in the public market at any given time at prevailing prices.

Shareholders may experience dilution from the exercise of outstanding options and warrants.

As of June 30, 2005, options and warrants to purchase 12,949,352 shares of common stock were outstanding at various exercise prices ranging from \$0.22 per share to \$8.00 per share. The issuance or potential issuance and sale of common stock upon the exercise of these options and warrants may adversely affect the market price of the common stock or result in substantial dilution to our existing stockholders.

Our management and principal stockholders together control more than 20% of our voting securities, a concentration of ownership which could delay or prevent a change in control.

As of June 30, 2005, our executive officers and directors beneficially own approximately 5% of our voting securities and our 5% or greater stockholders beneficially own approximately 16% of our voting securities. These stockholders, acting together, may be able to significantly influence any matters submitted for approval by our stockholders, including the election of directors, delaying or preventing a change of control, and the consideration of transactions in which stockholders might otherwise receive a premium for their shares over then current market prices.

We will face increased costs as a result of changes to the regulations governing public companies, including the Sarbanes-Oxley Act of 2002.

Enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules proposed by the Securities and Exchange Commission

and by the American Stock Exchange, could result in increased costs to us to evaluate the implications of any new rules and respond to their requirements. The new rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

[Table of Contents](#)

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

Interest Rate Risk. Our exposure to market risk related to changes in interest rates relates primarily to our investment portfolio. We invest in instruments that meet high credit quality standards, and we limit the amount of credit exposure as to any one issue, issuer and type of investments.

As of June 30, 2005, our cash and cash equivalents were \$15.7 million and investments, which consisted of mutual funds, were \$2.4 million. As of June 30, 2004, our cash and cash equivalents were \$17.9 million and investments, which consisted primarily of mutual funds, were \$2.5 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. A significant portion of the cost of manufacturing NeutroSpec is denominated in Euros. Therefore, a fluctuation in exchange rates between the Euro and the U.S. dollar would affect the Company's future cost of product revenues. The impact on the Company's future results of operations of any such change will be dependent on the volume and timing of the Company's future purchases. In addition, the Company incurs certain research and development costs denominated in foreign currency, which fluctuate from period to period.

As of June 30, 2005 and 2004, the amount of accounts payable and accrued expenses denominated in Euros was approximately \$0.8 million and \$0.9 million, respectively. Percentage increases in the U.S. dollar cost of Euros would result in corresponding increases in such liabilities. The Company has not hedged its exposures to foreign exchange fluctuations. However, the Company monitors its 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:

| | <u>Page</u> |
|---|--------------------|
| Report of Independent Registered Public Accounting Firm | 29 |
| Consolidated Balance Sheets | 30 |

| | |
|---|----|
| Consolidated Statements of Operations | 31 |
| Consolidated Statements of Cash Flows | 32 |
| Consolidated Statements of Stockholders' Equity | 33 |
| Notes to Consolidated Financial Statements | 34 |

[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, 2005 and 2004, 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, 2005. 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, 2005 and 2004, and the results of their operations and their cash flows for each of the years in the three-year period ended June 30, 2005, in conformity with U.S. generally accepted accounting principles.

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, 2005, 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 13, 2005 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 13, 2005

[Table of Contents \(Financial\)](#)

PALATIN TECHNOLOGIES, INC.

Consolidated Balance Sheets

ASSETS

Current assets:

| | | |
|---|---------------|---------------|
| Cash and cash equivalents | \$ 15,720,364 | \$ 17,947,076 |
| Available for sale investments | 2,385,570 | 2,465,350 |
| Accounts receivable | 5,441,425 | - |
| Inventories | 1,382,160 | - |
| Prepaid expenses and other current assets | 1,889,269 | 428,917 |

| | | |
|----------------------|------------|------------|
| Total current assets | 26,818,788 | 20,841,343 |
|----------------------|------------|------------|

| | | |
|-----------------------------|-----------|-----------|
| Property and equipment, net | 6,464,324 | 6,356,089 |
| Restricted cash | 475,000 | 428,075 |
| Other assets | 1,408,158 | 174,930 |

| | | |
|--------------|---------------|---------------|
| Total assets | \$ 35,166,270 | \$ 27,800,437 |
|--------------|---------------|---------------|

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

| | | |
|--|-----------|-----------|
| Capital lease obligations, current portion | \$ 11,269 | \$ 33,491 |
| Accounts payable | 4,773,297 | 2,019,970 |
| Accrued expenses | 3,925,406 | 2,461,605 |
| Accrued compensation | 545,870 | 599,600 |
| Deferred revenue, current portion | 3,790,828 | 242,000 |

| | | |
|---------------------------|------------|-----------|
| Total current liabilities | 13,046,670 | 5,356,666 |
|---------------------------|------------|-----------|

| | | |
|---|-----------|-----------|
| Capital lease obligations, net of current portion | 18,934 | 30,203 |
| Deferred rent, net of current portion | 3,001,980 | 3,026,928 |
| Deferred revenue, net of current portion | 9,873,438 | - |

| | | |
|-------------------|------------|-----------|
| Total liabilities | 25,941,022 | 8,413,797 |
|-------------------|------------|-----------|

Commitments and contingencies (Note 8)

Stockholders' equity:

| | | |
|---|---------------|---------------|
| Preferred stock of \$.01 par value - authorized 10,000,000 shares; Series A Convertible; issued and outstanding 11,447 and 11,697 shares as of June 30, 2005 and 2004, respectively | 114 | 117 |
| Common stock of \$.01 par value - authorized 150,000,000 shares; issued and outstanding 54,236,544 and 52,790,589 shares as of June 30, 2005 and 2004, respectively | 542,365 | 527,906 |
| Additional paid-in capital | 140,167,431 | 136,148,482 |
| Deferred compensation | - | (78,407) |
| Accumulated other comprehensive loss | - | (84,772) |
| Accumulated deficit | (131,484,662) | (117,126,686) |

| | | |
|----------------------------|-----------|------------|
| Total stockholders' equity | 9,225,248 | 19,386,640 |
|----------------------------|-----------|------------|

| | | |
|--|---------------|---------------|
| Total liabilities and stockholders' equity | \$ 35,166,270 | \$ 27,800,437 |
|--|---------------|---------------|

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

Consolidated Statements of Operations

Year Ended June 30,

| | 2005 | 2004 | 2003 |
|---|-----------------------|-----------------------|-----------------------|
| REVENUES: | | | |
| Royalties | \$ 1,586,050 | \$ - | \$ - |
| Product sales | 2,474,325 | - | - |
| Licenses, grants and contracts | 13,896,818 | 2,315,158 | 1,270,015 |
| Total revenues | 17,957,193 | 2,315,158 | 1,270,015 |
| OPERATING EXPENSES: | | | |
| Cost of product sales | 534,932 | - | - |
| Royalties | 328,401 | - | - |
| Research and development | 25,045,279 | 23,333,329 | 17,439,191 |
| General and administrative | 7,460,607 | 5,739,519 | 4,866,642 |
| Total operating expenses | 33,369,219 | 29,072,848 | 22,305,833 |
| Loss from operations | (15,412,026) | (26,757,690) | (21,035,818) |
| OTHER INCOME (EXPENSE): | | | |
| Investment income | 488,262 | 221,644 | 247,552 |
| Interest expense | (14,487) | (22,649) | (22,038) |
| Total other income, net | 473,775 | 198,995 | 225,514 |
| Loss before income taxes | (14,938,251) | (26,558,695) | (20,810,304) |
| Income tax benefit | 580,275 | 240,836 | 245,093 |
| NET LOSS | (14,357,976) | (26,317,859) | (20,565,211) |
| DEEMED DIVIDEND | - | - | (203,138) |
| NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS | \$(14,357,976) | \$(26,317,859) | \$(20,768,349) |
| Basic and diluted net loss per common share | \$ (0.27) | \$ (0.55) | \$ (0.73) |
| Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share | 53,861,182 | 47,687,679 | 28,362,121 |

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

| | 2005 | 2004 | 2003 |
|--|------|------|------|
|--|------|------|------|

CASH FLOWS FROM OPERATING ACTIVITIES:

| | | | |
|---|----------------|----------------|----------------|
| Net loss | \$(14,357,976) | \$(26,317,859) | \$(20,565,211) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 1,075,306 | 1,097,442 | 986,984 |
| Realized loss on investments | 114,551 | 129,355 | - |
| Stock-based compensation | 983 | 748,582 | 57,593 |
| Changes in certain operating assets and liabilities: | | | |
| Accounts receivable | (5,441,425) | - | - |
| Inventories | (1,382,160) | - | - |
| Prepaid expenses and other | (2,422,621) | (102,962) | (91,858) |
| Accounts payable | 2,753,327 | 675,181 | (234,547) |
| Accrued expenses and other | 1,174,199 | 193,448 | 342,073 |
| Deferred revenues | 13,422,266 | (165,420) | (386,598) |
| Net cash used in operating activities | (5,063,550) | (23,742,233) | (19,891,564) |

CASH FLOWS FROM INVESTING ACTIVITIES:

| | | | |
|---|-----------|-----------|-------------|
| Sale or maturity of investments | 50,000 | 1,420,712 | 9,464 |
| Purchases of investments | - | - | (2,979,917) |
| Purchases of property and equipment | (968,001) | (197,541) | (1,134,015) |
| Net cash (used in) provided by investing activities | (918,001) | 1,223,171 | (4,104,468) |

CASH FLOWS FROM FINANCING ACTIVITIES:

| | | | |
|---|-----------|------------|------------|
| Payments on capital lease obligations | (33,491) | (200,753) | (153,473) |
| Proceeds from common stock, stock option and warrant issuances, net | 3,788,330 | 26,372,288 | 30,499,844 |
| Net cash provided by financing activities | 3,754,839 | 26,171,535 | 30,346,371 |

NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS

| | | | |
|--|-------------|-----------|-----------|
| | (2,226,712) | 3,652,473 | 6,350,339 |
|--|-------------|-----------|-----------|

CASH AND CASH EQUIVALENTS, beginning of year

| | | | |
|--|------------|------------|-----------|
| | 17,947,076 | 14,294,603 | 7,944,264 |
|--|------------|------------|-----------|

| | | | |
|--|---------------|---------------|---------------|
| CASH AND CASH EQUIVALENTS, end of year | \$ 15,720,364 | \$ 17,947,076 | \$ 14,294,603 |
|--|---------------|---------------|---------------|

SUPPLEMENTAL CASH FLOW INFORMATION:

| | | | |
|---|------------|-----------|--------------|
| Cash paid for interest | \$ 14,171 | \$ 22,649 | \$ 22,038 |
| Assets acquired by capital lease | \$ - | \$ - | \$ 417,920 |
| Tenant allowances recognized in deferred rent | \$ 210,924 | \$ - | \$ 4,254,529 |
| Common stock issued for license fees | \$ 317,900 | \$ - | \$ - |

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

PALATIN TECHNOLOGIES, INC.

Consolidated Statements of Stockholders' Equity

| | Preferred Stock | | Common Stock | | Accumulated | | Other | Accumulated | Total |
|---|-----------------|----------|--------------|-----------|----------------------------|-----------------------|--------------|-----------------|--------------|
| | Shares | Amount | Shares | Amount | Additional Paid-in Capital | Deferred Compensation | | | |
| Balance, July 1, 2002 | 726,192 | \$ 7,262 | 17,423,076 | \$174,231 | \$ 78,792,240 | \$(53,942) | \$ 10,604 | \$(70,243,616) | \$ 8,686,779 |
| Issuance of common shares, net of expenses | - | - | 24,352,099 | 243,521 | 30,127,905 | - | - | - | 30,371,426 |
| Issuance of common shares upon conversion of preferred shares | (711,325) | (7,113) | 1,121,576 | 11,216 | (4,103) | - | - | - | - |
| Issuance of common shares upon exercise of options and warrants | - | - | 97,299 | 973 | 127,445 | - | - | - | 128,418 |
| Stock-based compensation | - | - | - | - | 41,628 | (13,153) | - | - | 28,475 |
| Amortization of deferred compensation | - | - | - | - | - | 29,118 | - | - | 29,118 |
| Unrealized loss on investments | - | - | - | - | - | (22,409) | - | (22,409) | - |
| Net loss | - | - | - | - | - | (20,565,211) | (20,565,211) | - | - |
| Balance, June 30, 2003 | 14,867 | 149 | 42,994,050 | \$429,941 | 109,085,115 | (37,977) | (11,805) | (90,808,827) | 18,656,596 |
| Issuance of common shares, net of expenses | - | - | 6,992,500 | 69,925 | 20,889,594 | - | - | - | 20,959,519 |
| Issuance of common shares upon conversion of preferred shares | (3,170) | (32) | 120,465 | 1,205 | (1,173) | - | - | - | - |
| Issuance of common shares upon exercise of options and warrants | - | - | 2,683,574 | 26,835 | 5,385,934 | - | - | - | 5,412,769 |
| Stock-based compensation | - | - | - | - | 789,012 | (86,157) | - | - | 702,855 |
| Amortization of deferred compensation | - | - | - | - | - | 45,727 | - | - | 45,727 |
| Unrealized loss on investments | - | - | - | - | - | (72,967) | - | (72,967) | - |
| Net loss | - | - | - | - | - | (26,317,859) | (26,317,859) | - | - |
| Balance, June 30, 2004 | 11,697 | 117 | 52,790,589 | 527,906 | 136,148,482 | (78,407) | (84,772) | (117,126,686) | 19,386,640 |
| Issuance of common shares, net of expenses | - | - | 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 |
| Issuance of common shares upon conversion of preferred shares | (250) | (3) | 9,505 | 95 | (92) | - | - | - | - |
| Issuance of common shares upon 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 |
| Loss on investments | - | - | - | - | - | 84,772 | - | 84,772 | - |
| Net loss | - | - | - | - | - | (14,357,976) | (14,357,976) | - | - |
| Balance, June 30, 2005 | 11,447 | \$ 114 | 54,236,544 | \$542,365 | \$140,167,431 | \$ - | \$ - | \$(131,484,662) | \$ 9,225,248 |

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

PALATIN TECHNOLOGIES, INC.
Notes to Consolidated Financial Statements

(1) ORGANIZATION

Nature of Business – Palatin Technologies, Inc. (“Palatin” or the “Company”) is a biopharmaceutical company focused on discovering and developing melanocortin (“MC”)-based therapeutics, which the Company believes is one of the fastest growing areas of pharmaceutical research and development. The MC family of receptors has been identified with a variety of conditions and diseases, including sexual dysfunction, obesity, cachexia (extreme wasting, generally secondary to a chronic disease) and inflammation. The Company’s objective is to become a worldwide leader in MC-based therapeutics by pursuing a strategy based on commercializing the Company’s products under development and identifying new product targets through the utilization of the Company’s patented

drug discovery platform.

In July 2004, the Company received approval from the U.S. Food and Drug Administration (“FDA”) to market NeuroSpec™, a proprietary radiolabeled monoclonal antibody product, for imaging and diagnosing equivocal appendicitis. NeuroSpec is marketed and distributed by the Company’s strategic collaboration partner, Mallinckrodt Imaging, a business unit of Tyco Healthcare (“Mallinckrodt”). The Company is currently conducting additional clinical trials with NeuroSpec and evaluating its market 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 infection.

PT-141, an MC receptor agonist and the Company’s lead therapeutic drug candidate, is a patented, nasally-administered peptide that is in clinical development for the treatment of both male and female sexual dysfunction. The Company completed various Phase 1 safety studies and Phase 2A and Phase 2B efficacy studies in male subjects and patients. The Company also completed a Phase 1 safety study in female subjects and a Phase 2A efficacy study in female patients with female sexual dysfunction. In August 2004, the Company entered into a Collaborative Development and Marketing Agreement with King Pharmaceuticals, Inc. (“King”), a specialty pharmaceutical company, to jointly develop and commercialize PT-141.

MIDAS™, a proprietary drug development platform technology, is utilized to design compounds that interact with the MC family of receptors. Through MIDAS™, the Company has identified several compounds that are now in preclinical development as potential treatments for obesity and cachexia, and a non-MC compound for congestive heart failure.

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 investigation, 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 its NeuroSpec and PT-141 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 incurred a net loss of \$14,357,976 for the year ended June 30, 2005 and has an accumulated deficit of \$131,484,662 as of June 30, 2005. The Company anticipates incurring additional losses in the future as it conducts clinical trials for other indications of NeuroSpec and continues research and development of PT-141 and its MIDAS™ technology. 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 has cash and cash equivalents of \$15,720,364 and investments of \$2,385,570 as of June 30, 2005. The Company expects that its existing capital resources will be adequate to fund the

[Table of Contents](#)

Company’s projected operations through its year ending June 30, 2006, based on current and projected expenditure levels. 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.

Concentrations – Concentrations in the Company’s assets and operations subject it to certain related risks. Financial instruments that potentially subject the Company to concentrations of credit risk primarily consist of cash and cash equivalents, short-term 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 as of June 30, 2005 consists of approximately \$1,451,000 due from Mallinckrodt and \$3,990,000 due from King under its collaboration agreements.

Revenue from King represented 64%, 0% and 0% of the Company’s total revenue in the years ended June 30, 2005, 2004 and 2003, respectively, and revenue from Mallinckrodt represented 36%, 94% and 89% of the Company’s total revenue in the years ended June 30, 2005, 2004 and 2003, respectively.

(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. As of June 30, 2005 and 2004, \$475,000 and \$428,075, respectively, of cash was restricted to secure letters of credit for security deposits on leases.

Investments – The Company accounts for its investments in accordance with Statement of Financial Accounting Standards (“SFAS”) 115, “Accounting For Certain Investments in Debt and Equity Securities.” The Company classifies such investments as available for sale investments and all such investments are recorded at fair value. Unrealized holding gains and losses, net of the related tax effect, if any, are excluded from earnings and are reported in other comprehensive loss and as a separate component of stockholders’ equity 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, marketable securities, accounts receivable and accounts payable. Management believes that the carrying value of these assets and liabilities are representative of their respective fair values.

Inventories – The Company’s inventories are related to NeutroSpec. Inventories are valued at the lower of cost or market using the first-in, first-out method and exclude certain costs incurred prior to the FDA approval of NeutroSpec in July 2004, which were charged directly to research and development

[Table of Contents](#)

expense. Inventory costs consist primarily of costs to third-party vendors and do not include general and administrative costs. As of June 30, 2005, all inventories consist of work-in-progress materials.

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 lab 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. 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 its long-lived assets, management evaluates the probability that future undiscounted net cash flows, without interest charges, will be less than the carrying amount of the assets. 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 discounted cash flows based on reasonable and supportable assumptions.

Other Assets – Other assets includes certain license fee payments related to PT-141 and the Company's collaborative agreement with King, which are being amortized over the period in which the Company performs certain development activities under the agreement.

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 recognition of rent expense on a straight-line basis for the buildings the Company occupies as well as the value of tenant allowances. Rent expense is being recognized ratably over the life of the leases.

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

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

Revenue from corporate collaborations and licensing agreements consists of up-front fees, research and development funding, and milestone payments. Non-refundable up-front fees are deferred and amortized to revenue over the related performance period. The Company estimates the performance period as the period in which it performs certain development activities under the applicable agreement. 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. Milestones are based on the occurrence of a substantive element specified in the contract or as a measure of substantive progress towards completion under the contract. Grant and other contract revenues are recognized as the Company provides the services stipulated in the underlying grants and/or contracts based on the time and materials incurred.

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.

Stock Options – The Company applies 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. Under this method, compensation cost is recorded only if the current 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, as amended in SFAS 148, "Accounting for Stock-Based Compensation — Transition and Disclosure," the Company has elected to continue to apply the intrinsic-value-based method of accounting described above, and has adopted only the disclosure requirements of SFAS 123.

The Company applies APB 25 and the related interpretations in accounting for its stock options. Had compensation cost for the Company's common stock options been determined based upon the fair value of the options at the date of grant, as prescribed under SFAS 123 and using the Black-Scholes option-pricing model, the Company's net loss attributable to common stockholders and net loss per common share would have been equal to the following pro forma amounts for the years ended June 30, 2005, 2004 and 2003:

| | 2005 | 2004 | 2003 |
|---|----------------|----------------|----------------|
| | ----- | ----- | ----- |
| Net loss attributable to common stockholders: | | | |
| As reported | \$(14,357,976) | \$(26,317,859) | \$(20,768,349) |
| Stock-based employee compensation expense included in the determination of net loss as reported | (15,879) | 626,639 | - |
| Impact of total stock-based compensation expense determined under fair-value-based method | (1,067,519) | (1,801,218) | (1,297,069) |
| | ----- | ----- | ----- |
| Pro forma | \$(15,441,374) | \$(27,492,438) | \$(22,065,418) |
| | ===== | ===== | ===== |
| Basic and diluted net loss per common share: | | | |
| As reported | \$ (0.27) | \$ (0.55) | \$ (0.73) |
| | ===== | ===== | ===== |
| Pro forma | \$ (0.29) | \$ (0.58) | \$ (0.78) |
| | ===== | ===== | ===== |
| Weighted average valuation assumptions: | | | |
| Expected life of options in years | 7 | 7 | 7 |
| Risk-free interest rate | 3.9% | 3.7% | 3.5% |
| Expected volatility | 87% | 91% | 101% |
| Expected dividend yield | 0% | 0% | 0% |

The Company accounts for options granted to consultants in accordance with EITF 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 consultants' 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 are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

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

Net Loss per Common Share – The Company applies SFAS 128, "Earnings per Share", which requires dual presentation of basic and diluted earnings per share ("EPS") for complex capital structures on

[Table of Contents](#)

the face of the statement of operations. Basic EPS is computed by dividing the income (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, such as stock options and warrants. For the years ended June 30, 2005, 2004 and 2003 there were no dilutive effects of stock options or warrants as the Company incurred a net loss in each period. Common shares issuable upon conversion of Series A Convertible Preferred Stock and the exercise of outstanding options and warrants amounted to an aggregate of 13,384,915, 12,837,094, and 15,705,708 as of June 30, 2005, 2004 and 2003, respectively.

Development Stage Enterprise — Beginning with the Company's current fiscal year, the Company is no longer considered to be a development-stage enterprise for accounting purposes. As a result, certain related disclosures and cumulative amounts presented in prior years have been omitted, as they are no longer required.

Reclassifications – Certain amounts in prior years' consolidated financial statements have been reclassified to conform to current year presentation.

The Company moved into its current research and office facilities in 2002. Prior to the current fiscal year, the Company classified tenant improvement allowances provided by its landlord as a reduction of leasehold improvements on its consolidated balance sheets. In a February 2005 letter to the American Institute of Certified Public Accountants, the Securities and Exchange Commission (the "SEC") clarified its position regarding certain lease accounting practices. Based upon the SEC's conclusions included in their letter, the Company has determined that its leasehold improvements should be recorded on a gross basis and the allowance received should be recorded as a deferred rent liability. Accordingly, the Company has increased leasehold improvements and recorded a deferred rent liability in a like amount. The deferred rent liability will be amortized over the lease term as a reduction of rent expense and the addition to leasehold improvements will be amortized over the lesser of the lease term or the useful life of the improvement. The June 30, 2004 consolidated balance sheet has been reclassified accordingly and the cash flow statements for the fiscal years ended June 30, 2004 and 2003 have been reclassified to include the amortization of the leasehold improvement with depreciation and amortization and the deferred rent liability with accrued expenses and other. The reclassifications did not have an effect on net income in the fiscal years ended June 30, 2005, 2004 or 2003.

Recently Issued Accounting Standards – In March 2004, the Financial Accounting Standards Board revised SFAS 123 by issuing SFAS 123(R), "Share-Based Payment." SFAS 123(R) replaces SFAS 123 and APB 25 and establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. SFAS 123(R) 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, and is effective as of the beginning of the first fiscal year that begins after June 15, 2005 for public entities that do not file as small business issuers. The Company has disclosed the pro forma impact on its earnings of adopting the fair value method of accounting for stock-based compensation under SFAS 123 in notes to its Consolidated Financial Statements for the years ended June 30, 2005, 2004, and 2003 above. The fair-value-based method of SFAS 123 is similar in most respects to the fair-value-based method under SFAS 123(R), however certain transition rules of SFAS 123(R) may affect the impact on the Company's consolidated financial position or results of operations. Such impact, if any, on the Company's consolidated financial position or results of operations has not yet been determined.

(3) AGREEMENTS WITH KING PHARMACEUTICALS, INC.

In August 2004, the Company entered into a Collaborative Development and Marketing Agreement with King, a specialty pharmaceutical company, to jointly develop and commercialize PT-141. Pursuant to the terms of the agreement, King and Palatin will share all collaboration development and marketing costs and all collaboration net profits derived from net sales of PT-141 in North America based on an agreed percentage. King and Palatin currently plan to seek a partner for PT-141 for territories outside of North America and will jointly share in collaboration development and marketing costs and all collaboration revenues generated from those territories. Palatin has the option to create, with King, a urology specialty sales force to co-promote the product in the U.S. if the product is successfully developed and commercialized.

[Table of Contents](#)

In August 2004, King paid the Company \$20,000,000 at the closing of the agreement and may pay potential milestone payments to the Company totaling up to \$100,000,000 for achieving certain male erectile dysfunction (“ED”) and female sexual dysfunction (“FSD”) development and regulatory approval targets. After regulatory approval and commercialization of PT-141, King may also pay milestone payments to the Company totaling up to an additional \$130,000,000 upon achieving specified annual North American net sales thresholds. A portion of the above milestones may be received in the form of equity contributions.

Of the \$20,000,000 payment received at closing, \$3,606,672 was recorded as an equity contribution and \$16,393,328 was recorded as deferred revenue to be recognized as revenue over the period of the Company’s performance during the initial development term of this agreement. The amount attributable to the equity contribution was 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. For the year ended June 30, 2005, the Company recognized \$3,360,394 of the deferred revenue.

(4) OTHER COMPREHENSIVE LOSS

Other comprehensive loss consists of the following:

| | For the year ended June 30, | | |
|--|-----------------------------|-----------------|-----------------|
| | 2005 | 2004 | 2003 |
| Net loss | \$ (14,357,976) | \$ (26,317,859) | \$ (20,565,211) |
| Unrealized loss on investments | (29,779) | (72,967) | (22,409) |
| Reclassification adjustment for realized losses included in net loss | 114,551 | - | - |
| Comprehensive loss | \$ (14,273,204) | \$ (26,390,826) | \$ (20,587,620) |

(5) INVESTMENTS

The following is a summary of available for sale investments:

| | June 30, 2005 | | | |
|--------------|---------------|------------------------|-------------------------|--------------|
| | Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| Mutual funds | \$ 2,385,570 | \$ - | \$ - | \$ 2,385,570 |
| Total | \$ 2,385,570 | \$ - | \$ - | \$ 2,385,570 |

| | June 30, 2004 | | | |
|---------------------------|---------------|------------------------|-------------------------|------------|
| | Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| Corporate debt securities | \$ 50,000 | \$ 521 | \$ - | \$ 50,521 |
| Mutual funds | 2,500,122 | - | (85,293) | 2,414,829 |

The Company determined that certain unrealized losses as of June 30, 2005 were other than temporary. Accordingly, the Company reduced the cost basis of the underlying security and recorded a realized loss of \$114,551 in its statement of operations for the quarter and year ended June 30, 2005.

(6) PROPERTY AND EQUIPMENT

Property and equipment, net, consists of the following:

[Table of Contents](#)

| | June 30, 2005 | June 30, 2004 |
|--|------------------|------------------|
| | ----- | ----- |
| Office equipment | \$ 1,508,402 | \$ 1,120,467 |
| Laboratory equipment | 2,393,236 | 2,292,039 |
| Leasehold improvements | 6,518,418 | 7,343,894 |
| | ----- | ----- |
| | 10,420,056 | 10,756,400 |
| Less: Accumulated depreciation and amortization | (3,955,732) | (4,400,311) |
| | ----- | ----- |
| | \$ 6,464,324 | \$ 6,356,089 |
| | ===== | ===== |

The cost of assets acquired under capital leases amounted to \$54,292 and \$417,920 as of June 30, 2005 and 2004, respectively, with accumulated amortization of \$29,861 and \$146,272 as of June 30, 2005 and 2004, respectively.

(7) ACCRUED EXPENSES

Accrued expenses consist of the following:

| | June 30, 2005 | June 30, 2004 |
|--------------------------------|------------------|------------------|
| | ----- | ----- |
| Product development costs | \$ 2,035,670 | \$ 1,079,000 |
| Deferred rent, current portion | 437,053 | 858,517 |
| Inventory production costs | 653,656 | - |
| Other | 799,027 | 524,088 |
| | ----- | ----- |
| | \$ 3,925,406 | \$ 2,461,605 |
| | ===== | ===== |

(8) COMMITMENTS AND CONTINGENCIES

Leases – The Company currently leases facilities in three buildings in New Jersey under non-cancelable operating leases. Future minimum lease payments under these leases are as follows:

| Year Ending June 30, | |
|----------------------|-------------|
| 2006 | \$1,823,753 |
| 2007 | 2,386,899 |
| 2008 | 2,072,281 |
| 2009 | 1,511,736 |
| 2010 | 1,514,345 |
| Thereafter | 3,837,583 |

For the years ended June 30, 2005, 2004 and 2003, rent expense was \$897,856, \$906,989 and \$1,147,112, respectively.

Capital Leases — In September 2002, the Company acquired laboratory equipment under capital leases. The term of these leases ranged from 24 to 60 months. As of June 30, 2005, \$30,203 remains outstanding pursuant to one lease obligation. Scheduled lease payments under this obligation are as follows:

| | |
|--------------------------------------|----------|
| Year Ending June 30, | |
| 2006 | \$13,549 |
| 2007 | 13,549 |
| 2008 | 6,775 |
| | ----- |
| Total | 33,873 |
| Amount representing imputed interest | (3,670) |
| | ----- |
| Net | \$30,203 |
| | ===== |

[Table of Contents](#)

Employment Agreements – The Company has employment agreements with four executives, which provide a stated annual compensation amount, subject to annual increases and annual bonus compensation, in an amount to be decided by the compensation committee and approved by the Company’s Board of Directors, based on achievement of yearly objectives and participation in all benefit programs that the Company establishes, to the extent the employee’s position, tenure, salary, age, health and other qualifications make him eligible to participate. Each agreement allows the Company or the employee to terminate the agreement upon written notice, and contains other provisions for termination by the Company for “cause”, or by the employee for “good reason” or due to a “change in control” (as these terms are defined in the employment agreements). Early termination may, in some circumstances, result in severance pay at the salary then in effect for a period of 18 to 24 months. 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, continuation of medical and dental benefits then in effect for 18 months, and immediate vesting of all stock options. Each agreement includes non-competition, non-solicitation and confidentiality covenants.

License Agreements – The Company has three license agreements that require minimum annual payments. As of June 30, 2005, future minimum payments under the license agreements amount to \$225,000 per year. The licenses also require royalties and other payments contingent on specified events.

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, 2005, 2004 and 2003, Company contributions amounted to \$149,236, \$109,015 and \$98,893, respectively.

Arbitration — On October 29, 2004, Competitive Technologies, Inc. (“CTI”) initiated an arbitration with the Company pursuant to the terms of the Company’s license agreement with CTI. In June 2005, in settlement of the dispute, the Company paid CTI \$1,700,000 in cash and issued to CTI 170,000 shares of the Company’s common stock with a fair market value of \$317,900.

(9) STOCKHOLDERS’ EQUITY

Series A Convertible Preferred Stock – As of June 30, 2005, 11,447 shares of Series A Convertible Preferred Stock, currently convertible into 435,555 shares of common stock, are 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, 2005, the Series A Conversion Price is \$2.63, so each share of Series A Convertible Preferred Stock is currently convertible into

approximately 38 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 \$1,144,700 in the aggregate as of June 30, 2005.

Common Stock Transactions – In January 2004, the Company concluded a private placement of common stock and warrants in which the Company sold 6,992,500 shares of its \$.01 par value common stock and 1,048,875 warrants, which equates to 15% warrant coverage on the number of shares sold, at an offering price of \$3.25 per share. Each five-year warrant entitles the holder to purchase one share of common stock at an exercise price of \$4.06 per share. The gross proceeds were approximately \$22,700,000

[Table of Contents](#)

and the net proceeds were approximately \$21,000,000. The Company made the private placement solely to financial institutions and accredited investors pursuant to Regulation D under the Securities Act of 1933. The investors represented that they were purchasing the securities for their own accounts for investment and not with a view toward resale or distribution to others. The certificates representing the shares of common stock and warrants bear restrictive legends. A registration statement covering the resale of the shares by the investors was filed and subsequently declared effective by the Securities and Exchange Commission in April 2004. In connection with the private placement, the Company paid placement fees totaling approximately \$1,700,000.

In private placements of common stock and warrants in July 2002, November 2002 and March 2003, the Company sold an aggregate of 24,352,099 shares of its common stock to investors consisting of domestic and European financial institutions and other accredited investors: 1,545,063 shares were sold at a market value of approximately \$1.17 per share in the July offering, 9,373,940 shares of common stock were sold at a market value of approximately \$1.23 per share in the November offering, and 13,433,096 shares of common stock were sold at a market value of approximately \$1.42 per share in the March offering. For every five shares purchased in the July and the November offerings, and for every four shares purchased in the March offering, the investors received a five-year warrant to purchase one share of common stock at an exercise price of \$1.46 for the July offering, \$1.54 for the November offering, and \$1.77 for the March offering. Based on the sales price of the common stock in these private placements, the exercise prices of certain outstanding warrants were adjusted downward in accordance with the existing terms of those warrants. As a result, a deemed dividend of \$203,138 has been reflected in the Company's consolidated statement of operations for the year ended June 30, 2003.

In connection with these private placements, the Company paid cash placement agent fees of \$126,000 for the July offering, \$790,433 for the November offering and \$985,250 for the March offering and issued five-year warrants to purchase (i) 103,004 shares of common stock at prices ranging from \$1.37 to \$1.46 per share pursuant to the July offering, and (ii) 458,647 shares of common stock at \$1.54 per share pursuant to the November offering.

Outstanding Stock Purchase Warrants – As of June 30, 2005, the Company had the following warrants outstanding (prices are rounded to the nearest cent).

| Common Stock Shares | Exercise Price per Share | Latest Termination Date |
|---------------------|--------------------------|-------------------------|
| 32,487 | \$0.22 | 09/13/05 |
| 38,627 | 1.37 | 07/29/07 |
| 154,506 | 1.46 | 06/13/07 |
| 1,410,273 | 1.54 | 11/29/07 |
| 2,464,789 | 1.77 | 03/21/08 |
| 32,654 | 1.78 | 02/15/06 |

| | | |
|-----------|------|----------|
| 404,263 | 2.36 | 06/25/06 |
| 134,188 | 2.66 | 10/29/06 |
| 1,057,864 | 2.70 | 04/30/07 |
| 292,215 | 2.75 | 06/13/07 |
| 15,000 | 2.82 | 05/13/12 |
| 30,000 | 2.90 | 04/06/06 |
| 50,000 | 2.97 | 11/30/07 |
| 25,000 | 3.38 | 11/30/07 |
| 25,000 | 3.65 | 12/17/06 |
| 15,000 | 4.00 | 12/15/10 |
| 1,041,750 | 4.06 | 01/28/09 |
| 235,225 | 4.25 | 08/18/07 |
| 87,884 | 6.53 | 10/27/05 |
| 216,000 | 6.60 | 10/05/05 |
| 146,475 | 7.42 | 10/27/05 |
| 352,000 | 7.50 | 10/05/05 |
| ----- | | |
| 8,261,200 | | |
| ===== | | |

[Table of Contents](#)

In December 2002, the Company issued warrants to purchase 15,000 shares of its common stock at \$2.82 per share to the Wistar Institute of Anatomy and Biology, as part of the consideration for a second agreement with Wistar to amend a technology license which Wistar had previously granted to the Company. The warrants expire in May 2012. The fair value of these warrants of approximately \$20,000, as calculated by the Black-Scholes option pricing model, has been included in general and administrative expenses in the year ended June 30, 2003.

In August 2004, the Company issued warrants to purchase 235,225 shares of its common stock at \$4.25 per share to King Pharmaceuticals, Inc. in connection with the companies' collaboration agreement described in Note 3 above.

In November 2004, the Company issued warrants to purchase 75,000 shares 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 warrants of

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

Stock Option 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 for up to 5,000,000 shares of common stock to employees, non-employee directors and consultants. 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, 2005, 4,980,700 shares were available for grant under the Plan.

As of June 30, 2005, there were 4,093 options available for grant under the 1996 Stock Option Plan, which expires in 2006. The 1996 Stock Option Plan is administered under the direction of the Board of Directors, which may specify grant terms and recipients. Options granted by the Company generally expire ten years from the date of grant and generally vest over three to four years.

The Company has also granted options under previous plans and under agreements with individuals, which were not under any plan.

Table of Contents

The following table summarizes option activity for the years ended June 30, 2005, 2004 and 2003:

| | 2005 | | 2004 | | 2003 | |
|---|--|-------------------|--|-------------------|--|-------------------|
| | Weighted Average Number of Shares | Exercise Price | Weighted Average Number of Shares | Exercise Price | Weighted Average Number of Shares | Exercise Price |
| Outstanding at beginning of year | 4,365,601 | \$3.58 | 4,136,237 | \$3.79 | 3,519,070 | \$4.30 |
| Granted | 661,933 | 2.45 | 957,500 | 3.34 | 799,900 | 1.73 |
| Exercised | (35,000) | 1.69 | (140,432) | 2.77 | (5,184) | 2.42 |
| Cancelled | (304,382) | 4.00 | (587,704) | 4.87 | (177,549) | 4.44 |
| Outstanding at end of year | 4,688,152 | 3.41 | 4,365,601 | 3.58 | 4,136,237 | 3.79 |
| Exercisable at end of year | 3,830,910 | 3.61 | 3,353,207 | 3.76 | 2,678,859 | 4.25 |
| Weighted average fair value of options granted during the year | | \$1.92 | | \$2.68 | | \$1.29 |

The following table summarizes options outstanding as of June 30, 2005:

| Range of Exercise Prices | Weighted Average Options Outstanding | Weighted Average Remaining Life (Years) | Weighted Option Exercise Price | Weighted Average Options Exercisable | Weighted Average Exercise Price |
|-----------------------------|--|---|---|---|--|
| \$1.00-\$2.49 | 1,170,796 | 8.0 | \$1.80 | 679,146 | \$1.69 |
| 2.50-3.99 | 2,140,600 | 6.3 | 3.18 | 1,800,000 | 3.18 |
| 4.00-5.99 | 1,116,781 | 5.1 | 4.73 | 1,091,781 | 4.74 |
| 6.00-8.00 | 259,975 | 2.3 | 6.91 | 259,983 | 6.91 |
| 1.00-8.00 | 4,688,152 | 6.2 | 3.41 | 3,830,910 | 3.61 |

During the year ended June 30, 2004, the Company made modifications to stock options held by an employee and a director. As a result of these modifications, the Company recorded expenses of (\$84,212) and \$156,239 during the years ended June 30, 2005 and 2004, respectively. In addition, there were stock options granted to certain officers that included vesting provisions which were contingent on achievement of certain performance objectives and one of these objectives was met in September 2003. As a result, in the years ended June 30, 2005 and 2004, a compensation expense charge in the amount of \$68,333 and \$470,400, respectively, was recorded in connection with these performance based options. As of June 30, 2005, options for 100,000 shares at an exercise price of \$1.99 per share were subject to vesting contingent on achievement of certain performance objectives.

(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 and research and development credits. Deferred tax assets and liabilities are determined based on the estimated

[Table of Contents](#)

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, 2005, the Company had Federal and state net operating loss carryforwards of approximately \$116,000,000 and \$85,000,000, respectively, which will begin to expire in 2006, if not utilized. As of June 30, 2005 the Company had federal research and development credits of approximately \$3,373,000 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, the Company's ability to utilize the aforementioned carryforwards may be limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes; therefore the Company may not be able to take full advantage of these carryforwards for federal income tax purposes.

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

| | June 30, 2005 | June 30, 2004 |
|---|------------------|------------------|
| | ----- | ----- |
| Net operating loss carryforwards | \$ 44,529,000 | \$ 43,344,000 |
| Research and development tax credits | 3,373,000 | 2,386,000 |
| Accrued expenses, deferred revenue and other | 5,094,000 | 798,000 |
| | ----- | ----- |
| | 52,996,000 | 46,528,000 |
| Valuation allowances | (52,996,000) | (46,528,000) |
| | ----- | ----- |
| 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, 2005 and 2004. The valuation allowance for the years ended June 30, 2005 and 2004 increased by \$6,468,000 and \$11,279,000, 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, 2005, 2004 and 2003, the Company sold New Jersey State operating loss carryforwards and research and development credits, which resulted in the recognition of \$580,275, \$240,836 and \$245,093, respectively, in tax benefits.

(11) RELATED PARTY TRANSACTIONS

One of the Company's directors is the president and sole stockholder of a company which provided strategic and technology consulting services. The Company paid the consulting firm \$0, \$43,125 and \$112,500 during the years ended June 30, 2005, 2004 and 2003, respectively, for consulting services provided to the Company.

(12) CONSOLIDATED QUARTERLY FINANCIAL DATA – UNAUDITED

The following tables provide quarterly data for the years ended June 30, 2005 and 2004:

| | Three Months Ended | | | |
|--|--------------------|-------------------|----------------------|-----------------------|
| | June 30, 2005 | March 31, 2005 | December 31, 2004 | September 30, 2004 |

(amounts in thousands, except share and per share data)

| | | | | |
|--|------------|------------|------------|------------|
| Total revenues | \$ 5,845 | 2,807 | \$ 4,813 | \$ 4,492 |
| Cost of product sales | 308 | 6 | 133 | 88 |
| Royalties | 84 | 85 | 87 | 72 |
| Other operating expenses | 10,588 | 6,813 | 7,623 | 7,482 |
| Total other income (expense) | 44 | 157 | 163 | 110 |
| Loss before income taxes | (5,091) | (3,940) | (2,867) | (3,040) |
| Income tax benefit | - | - | 580 | - |
| Net loss attributable to common stockholders | \$ (5,091) | \$ (3,940) | \$ (2,287) | \$ (3,040) |
| Basic and diluted net loss per common share | \$ (0.09) | \$ (0.07) | \$ (0.04) | \$ (0.06) |
| Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share | 54,056,264 | 54,021,372 | 53,997,547 | 53,375,147 |

| | Three Months Ended | | | |
|--|--------------------|-------------------|----------------------|-----------------------|
| | June 30, 2004 | March 31, 2004 | December 31, 2003 | September 30, 2003 |

(amounts in thousands, except share and per share data)

| | | | | |
|--|------------|------------|------------|------------|
| Total revenues | \$ 10 | 181 | \$ 291 | \$ 1,833 |
| Cost of product sales | - | - | - | - |
| Royalties | - | - | - | - |
| Other operating expenses | 6,945 | 8,292 | 5,203 | 8,633 |
| Total other income (expense) | (46) | 84 | 80 | 81 |
| Loss before income taxes | (6,981) | (8,027) | (4,832) | (6,719) |
| Income tax benefit | - | - | 241 | - |
| Net loss attributable to common stockholders | \$ (6,981) | \$ (8,027) | \$ (4,591) | \$ (6,719) |
| Basic and diluted net loss per common share | \$ (0.13) | \$ (0.16) | \$ (0.10) | \$ (0.16) |
| Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share | 52,687,077 | 50,455,484 | 44,531,302 | 43,161,281 |

[Table of Contents](#)**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

Item 9A. Controls and Procedures.

For the year ended June 30, 2005, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer (the principal finance and accounting officer), of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rules 13a – 15(e) and 15d – 15(e) under the Securities Exchange Act of 1934, as amended ("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, 2005, our disclosure controls and procedures have been designed and are being operated in a manner that provides reasonable assurance that the information required to be disclosed by the Company in reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. 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) promulgated under 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. There have not been any changes in our internal control over financial reporting during the quarter ended June 30, 2005 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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.

Palatin's management assessed the effectiveness of the Company's internal control over financial reporting as of June 30, 2005. 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 our assessment we believe that, as of June 30, 2005, 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 our 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, 2005, 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.

A company's internal control over financial reporting is a process designated 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, 2005, 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, 2005, based on the criteria established in Internal Control—Integrated Framework issued by 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, 2005 and 2004, 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, 2005, and our report dated September 13, 2005 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

Philadelphia, Pennsylvania

September 13, 2005

Item 9B. Other Information.

None.

PART III

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

- Item 10 – Directors and Executive Officers of the Registrant
- 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
- Item 14 – Principal Accountant Fees and Services

is incorporated by reference from our definitive proxy statement relating to the 2005 Annual Meeting of Stockholders, which we will file with the SEC within 120 days after our June 30, 2005 fiscal year end.

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: The following exhibits are filed with this report, or incorporated by reference as noted. Exhibits filed with this report are marked with an asterisk (*). Exhibits which consist of or include a management contract or compensatory plan or arrangement are marked with an obelisk (†).

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.
- 10.01 RhoMed Incorporated 1995 Employee Incentive Stock Option Plan. Incorporated by reference to Exhibit 10.04 of our annual report on Form 10-KSB for the year ended June 30, 1996, filed with the SEC on September 27, 1996. †
- 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 Form S-8 filed with the SEC on June 17, 1998. †
- 10.04 Executive Officers Stock Option Agreement. Incorporated by reference to Exhibit 4.18 of our Form S-8 filed with the SEC on June 17, 1998. †

[Table of Contents](#)

- 10.05 Form of Placement Agent Warrant for the RhoMed common stock offering. Incorporated by reference to Exhibit 10.22 of our annual report on Form 10-KSB for the year ended June 30, 1996, filed with the SEC on September 27, 1996.
- 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.
- 10.09 Form of warrant issued to purchasers in the September-October 2000 private placement. Incorporated by reference to Exhibit 10.3 of our quarterly report on Form 10-Q for the quarter ended September 30, 2000, filed with the SEC on November 14, 2000.
- 10.11 Employment Agreement dated as of October 1, 2003, between Palatin Technologies, Inc. and Carl Spana. Incorporated by reference to Exhibit 10.1 of our quarterly report on Form 10-Q for the quarter ended September 30, 2003, filed with the SEC on November 14, 2003. †
- 10.12 Employment Agreement dated as of October 1, 2003, between Palatin Technologies, Inc. and Stephen T. Wills. Incorporated by reference to Exhibit 10.2 of our quarterly report on Form 10-Q for the quarter ended September 30, 2003, filed with the SEC on November 14, 2003. †
- 10.13 Employment Agreement dated as of October 1, 2003, between Palatin Technologies, Inc. and Shubh D. Sharma. Incorporated by reference to Exhibit 10.3 of our quarterly report on Form 10-Q for the quarter ended September 30, 2003, filed with the SEC on November 14, 2003. †

- 10.14 Form of stock purchase agreement for our October 2001 private placement. Incorporated by reference to Exhibit 10.1 of our quarterly report on Form 10-Q for the quarter ended September 30, 2001, filed with the SEC on November 14, 2001.
- 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.
- 10.16 Form of warrant issued to purchasers in our October 2001 private placement. Incorporated by reference to Exhibit 10.3 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.

[Table of Contents](#)

- 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.

[Table of Contents](#)

- 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.
- 10.26 Development and Manufacturing Agreement between Palatin and DSM Biologics Company B.V. 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. 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.
- 10.27 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.
- 10.30 Employment Agreement dated as of May 1, 2005, between Palatin Technologies, Inc. and Trevor Hallam. †*
- 10.31 2005 Stock Plan. Incorporated by reference to Exhibit 10.01 of our report on Form 8-K, filed with the SEC on June 10, 2005. †
- 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, plan or arrangement.

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 13, 2005

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

| Signature | Title | Date |
|---|--|--------------------|
| <u>/s/ Carl Spana</u> Carl Spana | President, Chief Executive Officer and Director (principal executive officer) | September 13, 2005 |
| <u>/s/ Stephen T. Wills</u> Stephen T. Wills | Executive Vice President and Chief Financial Officer (principal financial and accounting officer) | September 13, 2005 |
| <u>/s/ John K.A. Prendergast</u> John K.A. Prendergast | Chairman and Director | September 13, 2005 |
| <u>/s/ Perry B. Molinoff</u> Perry B. Molinoff | Director | September 13, 2005 |
| <u>/s/ Robert K. deVeer, Jr.</u> Robert K. deVeer, Jr. | Director | September 13, 2005 |
| <u>/s/ Zola P. Horovitz</u> Zola P. Horovitz | Director | September 13, 2005 |
| <u>/s/ Robert I. Taber</u> Robert I. Taber | Director | September 13, 2005 |
| <u>/s/ Errol DeSouza</u> Errol DeSouza | Director | September 13, 2005 |

EXHIBIT LIST

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.
- 10.01 RhoMed Incorporated 1995 Employee Incentive Stock Option Plan. Incorporated by reference to Exhibit 10.04 of our annual report on Form 10-KSB for the year ended June 30, 1996, filed with the SEC on September 27, 1996. †

- 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 Form S-8 filed with the SEC on June 17, 1998. †
- 10.04 Executive Officers Stock Option Agreement. Incorporated by reference to Exhibit 4.18 of our Form S-8 filed with the SEC on June 17, 1998. †
- 10.05 Form of Placement Agent Warrant for the RhoMed common stock offering. Incorporated by reference to Exhibit 10.22 of our annual report on Form 10-KSB for the year ended June 30, 1996, filed with the SEC on September 27, 1996.
- 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.
- 10.09 Form of warrant issued to purchasers in the September-October 2000 private placement. Incorporated by reference to Exhibit 10.3 of our quarterly report on Form 10-Q for the quarter ended September 30, 2000, filed with the SEC on November 14, 2000.
- 10.11 Employment Agreement dated as of October 1, 2003, between Palatin Technologies, Inc. and Carl Spana. Incorporated by reference to Exhibit 10.1 of our quarterly report on Form 10-Q for the quarter ended September 30, 2003, filed with the SEC on November 14, 2003. †
- 10.12 Employment Agreement dated as of October 1, 2003, between Palatin Technologies, Inc. and Stephen T. Wills. Incorporated by reference to Exhibit 10.2 of our quarterly report on Form 10-Q for the quarter ended September 30, 2003, filed with the SEC on November 14, 2003. †
- 10.13 Employment Agreement dated as of October 1, 2003, between Palatin Technologies, Inc. and Shubh D. Sharma. Incorporated by reference to Exhibit 10.3 of our quarterly report on Form 10-Q for the quarter ended September 30, 2003, filed with the SEC on November 14, 2003. †
- 10.14 Form of stock purchase agreement for our October 2001 private placement. Incorporated by reference to Exhibit 10.1 of our quarterly report on Form 10-Q for the quarter ended September 30, 2001, filed with the SEC on November 14, 2001.
- 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.
- 10.16 Form of warrant issued to purchasers in our October 2001 private placement. Incorporated by reference to Exhibit 10.3 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.
- 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.
- 10.26 Development and Manufacturing Agreement between Palatin and DSM Biologics Company B.V. 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. 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.
- 10.27 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.
- 10.30 Employment Agreement dated as of May 1, 2005, between Palatin Technologies, Inc. and Trevor Hallam. †*
- 10.31 2005 Stock Plan. Incorporated by reference to Exhibit 10.01 of our report on Form 8-K, filed with the SEC on June 10, 2005. †

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, plan or arrangement.

SUBSIDIARIES OF THE REGISTRANT

| <u>Name of subsidiary</u> | <u>State of Incorporation</u> | <u>Name Under Which Subsidiary Does Business</u> |
|---------------------------|-----------------------------------|--|
| RhoMed Incorporated | New Mexico | RhoMed Incorporated |

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Palatin Technologies, Inc.:

We consent to the incorporation by reference in the registration statements on Form S-8 (Nos. 333-57079 and 333-83876) and registration statements on Form S-3 (Nos. 333-33569, 333-56605, 333-64951, 333-72873, 333-84421, 333-52024, 333-54918, 333-74990, 333-100469, 333-101764, 333-104370 and 333-112908) of Palatin Technologies, Inc. of our reports dated September 13, 2005, with respect to the consolidated balance sheets of Palatin Technologies, Inc. and subsidiary as of June 30, 2005 and 2004, 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, 2005, management's assessment of the effectiveness of internal control over financial reporting as of June 30, 2005, and the effectiveness of internal control over financial reporting as of June 30, 2005, which reports appear in the June 30, 2005 annual report on Form 10-K of Palatin Technologies, Inc.

/s/ KPMG LLP

Philadelphia, Pennsylvania
September 13, 2005

EXHIBIT 31.1

Certification of Chief Executive Officer

I, Carl Spana, certify that:

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

Date: September 13, 2005

/s/ Carl Spana

Carl Spana, Chief Executive Officer

EXHIBIT 31.2

Certification of Chief Financial Officer

I, Stephen T. Wills, certify that:

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

Date: September 13, 2005

/s/ Stephen T. Wills

Stephen T. Wills, Chief Financial Officer

EXHIBIT 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

I, Carl Spana, President and Chief Executive Officer of Palatin Technologies, Inc., hereby certify, to my knowledge, that the annual report on Form 10-K for the period ending June 30, 2005 of Palatin Technologies, Inc. (the "Form 10-K") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Palatin Technologies, Inc.

Dated: September 13, 2005

/s/ Carl Spana

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

EXHIBIT 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 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

I, Stephen T. Wills, Executive Vice President and Chief Financial Officer of Palatin Technologies, Inc., hereby certify, to my knowledge, that the annual report on Form 10-K for the year ended June 30, 2005 of Palatin Technologies, Inc. (the "Form 10-K") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of Palatin Technologies, Inc.

Dated: September 13, 2005

/s/ Stephen T. Wills
Stephen T. Wills
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)