

PALATIN TECHNOLOGIES INC  
Form 424B3  
October 13, 2005

**PROSPECTUS**

**PALATIN TECHNOLOGIES, INC.**

4C Cedar Brook Drive

Cranbury, New Jersey 08512

(609) 495-2200

245,000 shares of common stock

Selling stockholders identified in this prospectus may sell up to 245,000 shares of common stock of Palatin Technologies, Inc. We will not receive any proceeds from the sale of these shares.

Our common stock is listed on The American Stock Exchange under the symbol PTN. On September 19, 2005, the closing price of the common stock was \$2.00.

Investing in our common stock involves a high degree of risk. You should purchase shares only if you can afford a complete loss of your investment. See **Risk Factors** beginning on page 7.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

*The date of this prospectus is October 13, 2005*

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## PROSPECTUS SUMMARY

**This is a summary of our business and this offering. For a more complete understanding of our business and this offering, you should read the entire prospectus and the documents incorporated by reference.**

### PALATIN S BUSINESS

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 NeutroSpec , 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.

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

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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 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

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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 NeuroSpec and Mallinckrodt agreed to pay us a transfer price on each product unit transferred to Mallinckrodt and a royalty on the net sales of NeuroSpec.

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 NeuroSpec'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

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Mallinckrodt an exclusive license to market and distribute NeuroSpec worldwide, excluding Europe. Under the terms of the amendment, Mallinckrodt and Palatin will jointly develop and commercialize NeuroSpec 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.

We believe that NeuroSpec 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 NeuroSpec'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

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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.

## **THE OFFERING**

Selling stockholders identified in this prospectus may sell up to 245,000 shares of our common stock, \$0.01 par value. The selling stockholders may sell their shares according to the plan of distribution described on page 21 of this prospectus. We will not receive any proceeds from the sale of these shares. We have paid certain expenses related to the registration of the common stock.

## **RISK FACTORS**

You should consider the following factors in evaluating our business, future prospects and this offering.

**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

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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 NeutroSpec does not achieve market acceptance, our business will suffer.**

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

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of NeutroSpec;
- cost-effectiveness of NeutroSpec 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 NeutroSpec 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 NeutroSpec 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,

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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 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

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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 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.

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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

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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

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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

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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.

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.

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**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.

**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.

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**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.

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**RISKS RELATED TO THE OFFERING**

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

The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. A variety of factors may affect the market price of our common stock. These include, but are not limited to:

- publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- delay or failure in initiating, completing or analyzing pre-clinical or clinical trials or unsatisfactory design or result of these trials;
- achievement or rejection of regulatory approvals by our competitors or by us;
- announcements of technological innovations or new commercial products by our competitors or by us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- regulatory developments in the U.S. and foreign countries;
- economic or other crises and other external factors;
- period-to-period fluctuations in our revenue and other results of operations;
- changes in financial estimates by securities analysts; and
- sales of our common stock.

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

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating

performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

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

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

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**Investors in this offering will suffer immediate dilution.**

As of June 30, 2005, we had a net tangible book value of \$9.2 million which yields a net tangible book value of approximately \$0.17 per share of common stock, assuming the conversion of all then convertible preferred stock and no exercise of any warrants or options. The net tangible book value per share is substantially less than the current market price per share. If you pay more than the net tangible book value per share for stock in this offering, you will suffer immediate dilution.

**As of June 30, 2005, there were 13,384,907 shares of common stock underlying outstanding dilutive securities, which if exercised or converted, could decrease the value of your shares.**

As of June 30, 2005, holders of our outstanding derivative securities had the right to acquire the following amounts of underlying common stock:

435,555 shares issuable on the conversion of immediately convertible preferred stock, for no further consideration;

8,261,200 shares issuable on the exercise of warrants, at exercise prices ranging from \$0.22 to \$7.50 per share;

4,688,152 shares issuable on the exercise of stock options, at exercise prices ranging from \$1.00 to \$8.00 per share.

If the holders convert or exercise those derivative securities, you may experience dilution in the net tangible book value of your common stock. In addition, the sale or availability for sale of the underlying shares in the marketplace could depress our stock price. We have registered or agreed to register for resale all of the underlying shares listed above. Holders of registered underlying shares could resell the shares immediately upon issuance, resulting in significant downward pressure on our stock.

**NOTE CONCERNING FORWARD-LOOKING STATEMENTS**

Statements in this prospectus, as well as oral statements that our officers, directors, or employees acting on our behalf may make, 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 prospectus do not constitute guarantees of future performance. Investors are cautioned that statements which are not strictly historical statements contained in this prospectus, including, without limitation,



current or future financial performance,  
management's plans and objectives for future operations,  
clinical trials and results, o product plans and performance,  
clinical trials and results, o product plans and performance,  
management's assessment of market factors, and  
statements regarding the our strategy and plans and those of our strategic partners,

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constitute forward-looking statements. These forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to be materially different from our historical results or from any results expressed or implied by forward-looking statements. Our future operating results are subject to risks and uncertainties and are dependent upon many factors, including, without limitation, the risks identified under the caption "Risk Factors," as well as in our other Securities and Exchange Commission filings. The statements we make in this prospectus are as of the date of this prospectus. We will not revise these forward-looking statements to reflect events or circumstances after the date of this prospectus or to reflect the occurrence of unanticipated events.

### **INCORPORATION OF INFORMATION BY REFERENCE**

We incorporate into this prospectus information contained in documents which we file with the Securities and Exchange Commission. We are disclosing important information to you by referring you to those documents. The information which we incorporate by reference is an important part of this prospectus, and certain information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below, and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934:

annual report on Form 10-K for the year ended June 30, 2005, filed on September 13, 2005

the description of our common stock contained in our registration statement on Form 8-A filed on December 13, 1999

You may obtain a free copy of any or all of the information incorporated by reference by writing or calling us. Please direct your request to:

Stephen T. Wills  
Chief Financial Officer  
Palatin Technologies, Inc.  
4C Cedar Brook Drive  
Cranbury, New Jersey 08512  
Telephone (609) 495-2200  
Fax (609) 495-2201

## WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements, registration statements and other information with the SEC. You may read and copy any materials we file at the SEC's Public Reference Room at 100 F St. NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is <http://www.sec.gov>. You can find information about Palatin on our website at <http://www.palatin.com>. Information found on our website is not part of this prospectus.

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## USE OF PROCEEDS

We will not receive any proceeds from the sale of common stock by the selling stockholders. All proceeds from the resale of such shares will go to the selling stockholders. See "Selling Stockholders" and "Plan of Distribution" below.

## SELLING STOCKHOLDERS

This prospectus covers offers and sales of the following shares of common stock:

75,000 shares underlying three-year warrants issued November 30, 2004 under a financial services consulting agreement, with exercise prices ranging from \$2.97 to \$3.375 per share; and

170,000 shares issued on June 27, 2005 pursuant to an arbitration settlement.

The following table provides information on the selling stockholders, their current beneficial ownership of our securities, the number of shares offered for each stockholder's account, and the amount and percentage of their beneficial ownership after this offering, assuming they sell all of the offered shares. Beneficial ownership here means direct or indirect voting or investment power over outstanding stock and stock which a person has the right to acquire now or within 60 days after the date of this prospectus. It therefore includes stock issuable on exercise of the warrants described above. The calculation of the percentage of common stock beneficially owned after the offering is based on 54,258,366 shares outstanding as of the date of this prospectus.

The information in the table is from the selling stockholders, reports furnished to us under rules of the SEC and our stock ownership records, as of the date of this prospectus. Except as noted in the footnotes, no selling stockholder has had, within the past three years, any position, office or other material relationship with us or any of our predecessors or affiliates.

Name of Selling Stockholder	Shares Beneficially Owned Before the Offering	Shares Offered	Shares Beneficially Owned After the Offering	% of Common Stock Beneficially Owned After the Offering
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Competitive Technologies, Inc. (1)	170,000	170,000	0	*
North Coast Securities Corporation(2)	7,500	7,500	0	*
Paul and Denise Kotos, JT (2)	67,500	67,500	0	*

\*less than 1%

- (1) We have a license agreement with Competitive Technologies, Inc. under which we exclusively license for a defined field certain compounds and methods developed at the University of Arizona.
- (2) Shares issuable on exercise of warrants. Paul and Denise Kotos are the owners of North Coast Securities Corporation, with which we had a financial services consulting agreement.

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### PLAN OF DISTRIBUTION

We have registered the shares on behalf of the selling stockholders. As used in this prospectus, the term "selling stockholders" includes transferees, donees, pledgees and other successors in interest who are selling shares received from selling stockholders after the date of this prospectus. We are bearing all costs relating to the registration of the shares, other than fees and expenses, if any, of counsel or other advisors to the selling stockholders. Any commissions, discounts, or other fees payable to broker-dealers in connection with any sale of the shares will be borne by the selling stockholders. The selling stockholders may offer their shares at various times in one or more of the following transactions, or in other kinds of transactions:

transactions on the American Stock Exchange;

in private transactions other than through the American Stock Exchange;

in connection with short sales of Palatin shares;

by pledge to secure debts and other obligations;

in connection with the writing of non-traded and exchange-traded call options, in hedge transactions and in settlement of other transactions;

in standardized or over-the-counter options; or

in a combination of any of the above transactions.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance on Rule 144 under the Securities Act, if they meet the criteria and conform to the requirements of that rule.

The selling stockholders may sell their shares at quoted market prices, at prices based on quoted market prices, at negotiated prices or at fixed prices. The selling stockholders may use broker-dealers to sell their shares. If this happens, broker-dealers may either receive discounts or commissions from the selling stockholders, or they may receive commissions from purchasers of shares for whom they acted as agents.

The selling stockholders and any broker-dealers or agents that participate with the selling stockholders in the sale of shares may be underwriters within the meaning of the Securities Act. Any commissions received by broker-dealers or agents on the sales and any profit on the resale of shares purchased by broker-dealers or agents may be deemed to be underwriting commissions or discounts under the Securities Act.

Under the rules and regulations of the SEC, any person engaged in the distribution or the resale of our shares may not simultaneously buy, bid for or attempt to induce any other person to buy or bid for our common stock in the open market for a period of two business days prior to the commencement of the distribution. The rules and regulations under the Securities Exchange Act of 1934 may limit the timing of purchases and sales of shares of our common stock by the selling stockholders.

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## LEGAL MATTERS

The legality of the shares of common stock offered in this prospectus has been passed upon by our counsel, Brian F. Lanter, Attorney at Law, P.C., Albuquerque, New Mexico. Mr. Lanter holds 295 shares of our common stock. We have granted Mr. Lanter an option under our 1996 Stock Option Plan to purchase 10,000 shares of common stock at \$4.00 per share, with an expiration date of February 6, 2011.

## EXPERTS

The consolidated financial statements of Palatin Technologies, Inc. and subsidiary as of June 30, 2005 and 2004, and for each of years in the three-year period ended June 30, 2005, and management's assessment of the effectiveness of internal control over financial reporting as of June 30, 2005, have been incorporated by reference herein and in the registration statement in reliance upon the reports of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

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This prospectus is part of a registration statement we filed with the Securities and Exchange Commission. You should rely only on the information or representations contained in this prospectus. We have not authorized anyone to provide information other than that provided in this prospectus. We have not authorized anyone to provide you with any information that is different. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of the document.

**245,000**

**Shares of Common Stock**

**Palatin Technologies, Inc.**

*The date of this prospectus is October 13, 2005*

**PROSPECTUS**