

KING PHARMACEUTICALS INC
Form 425
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PURSUANT TO RULE 425 UNDER THE SECURITIES ACT OF 1933
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THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

**SUBJECT COMPANY: KING PHARMACEUTICALS, INC.
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THE FOLLOWING IS A NEWS RELEASE ISSUED BY KING PHARMACEUTICALS, INC. ON AUGUST 13, 2004

N E W S R E L E A S E

FOR IMMEDIATE RELEASE

**KING PHARMACEUTICALS AND PALATIN TECHNOLOGIES ANNOUNCE
STRATEGIC ALLIANCE TO JOINTLY DEVELOP AND COMMERCIALIZE PT-141
AS AN INNOVATIVE TREATMENT FOR SEXUAL DYSFUNCTION**

BRISTOL, TN and CRANBURY, NJ August 13 , 2004 King Pharmaceuticals, Inc. (NYSE: KG) and Palatin Technologies, Inc. (AMEX: PTN) announced today that they have entered into a strategic alliance to jointly develop and, on obtaining necessary regulatory approvals, commercialize Palatin's PT-141 for the treatment of male and female sexual dysfunction.

PT-141 is the first compound in a new drug class called melanocortin receptor agonists under development to treat sexual dysfunction. This new chemical entity is being evaluated in phase II clinical trials studying the efficacy and safety profile of varying doses of this novel compound in men experiencing erectile dysfunction (ED) and women experiencing female sexual dysfunction (FSD). The mechanism of action of PT-141 may offer important benefits

over currently available products for the treatment of ED because it acts on the pathway that controls sexual function without acting directly on the vascular system. Clinical data indicates that PT-141 may be effective in treating a broad range of patients suffering from ED. The nasal formulation of PT-141 currently under development is as convenient as oral treatments, is more patient-friendly than invasive treatments for ED, such as injections and trans-urethral pellets, and appears to result in a rapid onset of action.

Although the current ED market is primarily served by PDE-5 inhibitors which target the vascular system, a substantial unmet medical need for alternative sexual dysfunction therapies exists. Many patients are contraindicated for, or non-responsive to, PDE-5 inhibitors. For example, unlike PDE-5 inhibitors which are contraindicated in patients taking nitrates, primarily for the treatment of cardiovascular disease, current clinical data indicates that PT-141 should not have any drug interactions with nitrates. Current literature indicates that about one half of all patients who receive an initial prescription for a PDE-5 inhibitor do not renew the prescription due chiefly to adverse side effects, drug interaction issues, and/or the lack of an acceptable level of responsiveness.

The companies believe that PT-141 will benefit from the success King has achieved in marketing Altace® (ramipril), the leading branded ACE (angiotensin converting enzyme) inhibitor according to IMS America prescription data, to a similar male patient population with its experienced sales force.

In connection with the transaction, King and Palatin entered into a collaborative agreement for the purpose of developing and commercializing PT-141. Pursuant to the terms of the agreement, Palatin has granted King a co-exclusive license with Palatin to PT-141 in North America and an exclusive right to collaborate in the licensing or sublicensing of PT-141 with Palatin outside North America. Palatin has the option to create a urology specialty sales force to co-promote the product in the U.S., upon commercialization. This transaction is expected to close before the end of this quarter.

King will pay Palatin \$20.0 million at closing, \$5.0 million of which will consist of an equity investment in Palatin.

In addition, upon achieving certain milestones, King could pay Palatin up to \$100.0 million for achieving certain ED and FSD development and regulatory approval targets, a portion of which could consist of additional equity investments in Palatin, at King's option. After regulatory approval and commercialization of PT-141, King may also pay potential one-time milestone payments to Palatin totaling up to \$130.0 million upon achieving specified annual North American net sales thresholds.

Under 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 will seek a partner for PT-141 for territories outside of North America and will jointly share in collaboration revenues generated from those territories.

Brian A. Markison, King's President and Chief Executive Officer, stated, "We are very excited to announce our collaborative agreement with Palatin to jointly develop and commercialize PT-141. This transaction exemplifies our

strategy to in-license promising novel branded prescription pharmaceutical products in development that have considerable market potential. PT-141 provides an excellent strategic fit, complementing our established primary care and cardiovascular franchises. Additionally, when considering our pending merger with Mylan Laboratories, Inc. and the potential strength of the combined core competencies of King and Mylan, our ability to optimize the commercial potential of PT-141 should be substantial. Moreover, with a composition of matter patent that extends through 2020, PT-141 has the potential to significantly enhance our company's long-term shareholder value.

Mr. Markison explained, PT-141's fast-acting nasal-spray delivery method and potentially superior drug interaction and safety profile, combined with a unique mechanism of action that targets the central nervous system, highly differentiates the product from currently marketed ED therapies. The vast size of the sexual dysfunction market is well recognized and we believe PT-141 has the promise to meet the substantial unmet needs of patients who are not able to successfully treat their ED with currently available products.

Carl Spana, Ph.D., President and Chief Executive Officer for Palatin, commented, This strategic alliance with King Pharmaceuticals is a validation of our company's outstanding accomplishments in research and development and represents a major milestone in value creation for our stockholders. In particular, this opportunity to jointly develop and commercialize PT-141 with King Pharmaceuticals will serve as a foundation for the continued development of Palatin as an emerging biopharmaceutical company.

Dr. Spana continued, This is a smart alliance that leverages each company's strengths. By combining Palatin's first-in-class ED product and melanocortin research and development expertise with King's demonstrated regulatory and manufacturing capabilities, plus its well-established primary care-physician and cardiovascular-specialist sales force, we believe the companies can truly maximize PT-141's potential.

About Erectile Dysfunction (ED)

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 psychogenic issues may contribute to ED. It is estimated that one half of all men over the age of 40 suffer from ED. About 150 million men worldwide and 30 million American men suffer from ED.

About Female Sexual Dysfunction (FSD)

FSD consists of four components, including hypoactive sexual desire disorder, female sexual arousal disorder, dyspareunia or painful intercourse and anorgasmia. A February 10, 1999 study published in the *Journal of the American Medical Association, JAMA*, titled, Sexual Dysfunction in the United States: Prevalence and Predictors,

states that some form of FSD is prevalent in approximately 43 percent of the female population.

Conference Call Information

King Pharmaceuticals and Palatin Technologies will host a joint conference call and webcast today at 11:30 am E.D.T. to discuss the collaborative agreement between the companies. Interested persons may listen to the conference call at <http://phx.corporate-ir.net/playerlink.zhtml?c=93939&s=wm&e=927763> or by dialing 800-795-1259 (US only), or 785-832-1508 (International), pass code KG. If you are unable to participate during the live webcast, the call will be archived on King's web site at www.kingpharm.com and Palatin's website www.palatin.com for not less than 15 days following the call. In addition, a replay of today's conference call will be available for 15 days beginning today, by dialing 800-839-4017 (US only) or 402-220-2984 (International).

About King Pharmaceuticals

King, headquartered in Bristol, Tennessee, is a vertically integrated branded pharmaceutical company. King, an S&P 500 Index company, seeks to capitalize on opportunities in the pharmaceutical industry through the development, including through in-licensing arrangements and acquisitions, of novel branded prescription pharmaceutical products in attractive markets and the strategic acquisition of branded products that can benefit from focused promotion and marketing and product life-cycle management. As previously reported, Mylan Laboratories Inc. and King have signed a definitive agreement under which Mylan will acquire King in a stock-for-stock transaction, creating a leading diversified specialty pharmaceutical company.

About Palatin Technologies, Inc.

Palatin Technologies, Inc. (AMEX: PTN) is a biopharmaceutical company focused on discovering and developing melanocortin (MC)-based therapeutics. NeutroSpec™, the Company's proprietary radiolabeled monoclonal antibody product for imaging and diagnosing infections, has been approved by the FDA as an imaging agent for the diagnosis of equivocal appendicitis. NeutroSpec is marketed and distributed by Palatin's strategic collaboration partner, Mallinckrodt Imaging, a business unit of Tyco Healthcare. The Company is currently conducting clinical trials with its lead drug PT-141, an MC receptor agonist, for the treatment of male and female sexual dysfunction. Palatin's patented drug discovery platform, MIDAS™, streamlines the drug design process with an efficient approach to identify lead compounds from protein targets for drugs. For further information, visit the Palatin web site at www.palatin.com.

Forward-looking Statements

This release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and as that term is defined in the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect managements' current views of future events and operations, including, but not limited to, statements pertaining to the potential development and commercialization of PT-141; statements pertaining to patent protection for PT-141; statements pertaining to the potential market for PT-141; statements pertaining to the potential safety and efficacy benefits of PT-141; statements pertaining to the potential value of this transaction to shareholders of King and Palatin; statements pertaining to the ability of King to

market PT-141 following regulatory approval; and statements pertaining to Mylan's anticipated acquisition of King. Some important factors which may cause results to differ materially from such forward-looking statements include dependence on the companies' abilities to carry out their respective business plans; dependence on the successful development and commercial acceptance of PT-141; dependence on the companies' abilities to fund development of PT-141; dependence on whether a commercial product results from PT-141 development activities; dependence on the extent of intellectual property protection for PT-141; dependence on the companies' abilities to establish and successfully complete clinical trials necessary for approval of PT-141 as a treatment for sexual dysfunction; dependence on the companies' abilities to successfully collaborate in the development and commercialization of PT-141; dependence on King's ability to successfully market PT-141; dependence on the availability and cost of raw materials; dependence on the unpredictability of the duration and results of the U.S Food and Drug Administration's (FDA) review of Investigational New Drug Applications (IND), New Drug Applications (NDA), and supplemental New Drug Applications, (sNDAs) and/or the review of other regulatory agencies worldwide; dependence on compliance with FDA and other government regulations that relate to King's and Palatin's respective businesses; dependence on King's and Palatin's abilities to successfully manufacture PT-141; dependence on the occurrence of all contingencies necessary to complete the closing of Mylan's acquisition of King; and dependence on changes in general economic and business conditions; changes in current pricing levels; changes in federal and state laws and regulations; changes in competition; unexpected changes in technologies and technological advances; and manufacturing capacity constraints. Other important factors that may cause actual results to differ materially from the forward-looking statements are discussed in the Risk Factors section and other sections of King's Form 10-K for the year ended December 31, 2003 and Form 10-Q for the second quarter ended June 30, 2004, and Palatin's Form 10-K for the year ended June 30, 2003 and Form 10-Q for the third quarter ended March 31, 2004, which are on file with the U.S. Securities and Exchange Commission. The companies do not undertake to publicly update or revise any of their forward-looking statements even if experience or future changes show that the indicated results or events will not be realized.

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In connection with the proposed transaction, King and Mylan will file relevant materials with the Securities and Exchange Commission ("SEC"), including one or more registration statement(s) that contain a prospectus and a joint proxy statement. Investors and security holders of King and Mylan are urged to carefully read those documents (when they become available) and any other relevant documents filed with the SEC, as well as any amendments or supplements to those documents, because those documents will contain important information about King, Mylan, the transaction and related matters. Investors and security holders may obtain those documents (and any other documents filed by King or Mylan with the SEC) free of charge at the SEC's website at www.sec.gov. In addition, the documents filed with the SEC by King may be obtained free of charge by directing such request to: King Pharmaceuticals, Inc., Attn: Corporate Affairs, 501 Fifth Street, Bristol, TN 37620. The documents filed with the SEC by Mylan may be obtained free of charge by directing such request to: Mylan Laboratories Inc., Attention: Investor Relations, 1500 Corporate Drive, Canonsburg, PA 15317. Investors and security holders are urged to read the joint proxy statement/prospectus and the other relevant materials when they become available before making any voting or investment decision with respect to the proposed transaction.

King, Mylan and their respective executive officers and directors may be deemed to be participants in the solicitation of proxies from the shareholders of King and Mylan in favor of the merger. Information about the executive officers and directors of King and their ownership of King common stock is set forth in the proxy statement for King's 2003 Annual Meeting of Shareholders, which was filed with the SEC on September 19, 2003, and in press releases, Forms 3 and 4 and Current Reports on Form 8-K for directors and executive officers who have since joined, or departed from, King. Information about the executive officers and directors of Mylan and their ownership of Mylan common stock is set forth in the proxy statement for Mylan's 2004 Annual Meeting of Shareholders, which was filed with the SEC on June 28, 2004, and in press releases and Forms 3 and 4 for directors and executive officers who have since joined, or departed from, Mylan. Investors and security holders may obtain more detailed information regarding the direct and indirect interests of King, Mylan and their respective executive officers and directors in the acquisition by reading the joint proxy statement/prospectus regarding the acquisition when it becomes available.