PALATIN TECHNOLOGIES INC Form S-1/A October 22, 2014

As filed with the Securities and Exchange Commission on October 22, 2014

Registration No. 333-198992

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

# AMENDMENT NO. 2 TO FORM S-1

# REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

# Palatin Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization) 2834

(Primary Standard Industrial Classification Code Number)

95-4078884 (I.R.S. Employer Identification Number)

# 4B Cedar Brook Drive Cranbury, New Jersey 08512 (609) 495-2200

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

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

(Name, address, including zip code, and telephone number, including area code, of agent for service)

# Copies to:

Faith L. Charles, Esq. Thompson Hine LLP 335 Madison Avenue, 12<sup>th</sup> Floor New York, New York 10017 (212) 344-5680 Stephen A. Slusher, Esq. Chief Legal Officer 4B Cedar Brook Drive Cranbury, New Jersey 08512 (609) 495-2200 Michael D. Maline, Esq. Goodwin Procter LLP 620 Eighth Avenue New York, New York 10018 (212) 813-8966

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.o

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.o

Copies to:

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.o

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

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

Copies to:

# **CALCULATION OF REGISTRATION FEE**

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price <sup>(1)</sup>	Amount of Registration Fee
Common Stock, \$0.01 par value per share <sup>(2)(3)</sup>	\$ 51,750,000	\$ 6,014.00
Common Stock Purchase Warrants <sup>(3)</sup>		(4)
Shares of Common Stock, \$0.01 par value per share, underlying		
Common Stock Purchase Warrants <sup>(2)</sup>		
Total Registration Fee	\$ 51,750,000	\$ 6,014.00 (5)

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.
- Pursuant to Rule 416, this registration statement shall be deemed to cover additional securities that may be offered or issued to prevent dilution resulting from stock splits, stock dividends or similar transactions.
  - (3) Includes shares the underwriters have the option to purchase to cover over-allotments, if any.
  - (4) No registration fee required pursuant to Rule 457(g) under the Securities Act of 1933, as amended. (5) Previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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

# Subject To Completion, Dated October 22, 2014

\$45,000,000 Units

PALATIN TECHNOLOGIES, INC.

Shares of Common Stock Warrants to Purchase up to Shares of Common Stock

# per Unit

Palatin Technologies, Inc. is offering units with each unit consisting of one share of our common stock and a shares of our common stock warrant to purchase (and the shares of our common stock issuable from time to time upon exercise of the offered warrants).

The last reported sale price for our common stock on October 21, 2014 was \$0.69.

Each warrant will have an exercise price of \$ share, will be exercisable upon issuance and will expire five years from the date of issuance. The units will not be
Trading symbol: NYSE MKT PTN issued or certificated. The shares of common stock and the warrants are immediately separable and will be issued separately, but will be purchased together in this offering.

#### This investment involves risks. See Risk Factors beginning on page 5.

	Per Share	Total
Public offering price	\$	\$
Underwriting discount and commissions	\$	\$
Proceeds, before expenses, to us <sup>(1)</sup>	\$	\$

We have agreed to reimburse the underwriters for fees incurred by them in connection with this offering, (1) up to a maximum of \$100,000. See Underwriting beginning on page 94 in this prospectus.

The underwriters have a 30-day option to purchase up to additional units from us to cover over-allotments, if any.

The underwriters expect to deliver the securities on or about , 2014.

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.

**Piper Jaffray** 

**Canaccord Genuity** 

**Noble Financial Capital Markets** 

The date of this prospectus is , 2014.

\$ per Unit 6

## TABLE OF CONTENTS

	Page
Prospectus Summary	<u>1</u>
Risk Factors	<u>5</u>
Special Note Concerning Forward-Looking Statements	<u>31</u>
<u>Use of Proceeds</u>	<u>33</u>
Market Price of Common Stock	<u>34</u>
<u>Dividend Policy</u>	<u>35</u>
Capitalization	<u>36</u>
<u>Dilution</u>	<u>37</u>
Management s Discussion and Analysis of Financial Condition and Results of Operations	<u>38</u>
<u>Business</u>	<u>44</u>
<u>Management</u>	<u>68</u>
Executive and Director Compensation	<u>73</u>
Certain Relationships and Related Transactions	<u>79</u>
Security Ownership of Certain Beneficial Owners and Management	<u>80</u>
<u>Description of Securities</u>	<u>84</u>
Material U.S. Tax Considerations For Non-U.S. Holders Of Common Stock	<u>90</u>
Underwriting	<u>94</u>
<u>Legal Matters</u>	<u>97</u>
<u>Experts</u>	<u>97</u>
Where You Can Find More Information	<u>97</u>
Incorporation of Certain Information By Reference	<u>98</u>
<u>Index to Financial Statements</u>	<u>F-1</u>

You should rely only on the information contained in this prospectus and any free writing prospectus prepared by us or on our behalf. We have not, and the underwriters have not, authorized anyone to provide you with different or additional information. If anyone provides you with different or additional information, you should not rely on it. The information in this prospectus is accurate only as of the date on the front of this prospectus. Our business, financial condition, results of operations and prospects may have changed since the date of this prospectus. This prospectus is not an offer or solicitation relating to the securities in any jurisdiction in which such an offer or solicitation relating to the securities is not authorized. You should not consider this prospectus to be an offer or solicitation relating to the securities if the person making the offer or solicitation is not qualified to do so, or if it is unlawful for you to receive such an offer or solicitation.

i

# PROSPECTUS SUMMARY

This summary highlights certain information appearing elsewhere in this prospectus. This summary is not complete and does not contain all of the information you should consider prior to investing in our securities. After you read this summary, you should read and consider carefully the more detailed information and financial statements and related notes that we include in this prospectus, especially the sections entitled Risk Factors and Management s Discussion and Analysis of Financial Condition and Results of Operation. If you invest in our securities, you are assuming a high degree of risk.

Unless we have indicated otherwise or the context otherwise requires, references in the prospectus to Palatin, the Company, we, us and our or similar terms refer to the operations of Palatin Technologies, Inc. and its subsidiary.

#### **Overview**

We are a biopharmaceutical company developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential. Our programs are based on molecules that modulate the activity of the melanocortin and natriuretic peptide receptor systems. Our primary product in clinical development is a combination drug-device product for the delivery of bremelanotide for the treatment of female sexual dysfunction, or FSD. In addition, we have drug candidates or development programs for obesity, erectile dysfunction, cardiovascular diseases, pulmonary diseases, inflammatory diseases and dermatologic diseases.

The following drug development programs are actively under development:

Bremelanotide, an on-demand subcutaneous injectable peptide melanocortin receptor agonist, for treatment of FSD in premenopausal women. Bremelanotide, which is a melanocortin agonist (a compound which binds to a cell receptor and activates a response), is a synthetic peptide analog of the naturally occurring hormone alpha-MSH (melanocyte-stimulating hormone). The novel mechanism of action involves activating endogenous melanocortin hormone pathways involved in sexual arousal response. Bremelanotide is scheduled to start Phase 3 clinical trials in the last quarter of calendar 2014;

Melanocortin receptor-4, or MC4r, compounds for treatment of obesity and diabetes in collaboration with AstraZeneca pursuant to our research collaboration and license agreement. Results of our studies involving MC4r peptides suggest that certain of these peptides may have significant commercial potential for treatment of conditions responsive to MC4r activation, including FSD, erectile dysfunction, obesity and diabetes;

PL-3994, a peptide mimetic natriuretic peptide receptor A, or NPR-A, agonist, for treatment of cardiovascular and pulmonary indications. PL-3994 is our lead natriuretic peptide receptor product candidate, and is a synthetic mimetic of the neuropeptide hormone ANP. PL-3994 is in development for treatment of heart failure, acute exacerbations of asthma and refractory hypertension; and

Melanocortin receptor-1, or MC1r, agonist peptides, for treatment of inflammatory and dermatologic disease indications. Our MC1r peptide drug candidates are highly specific, with substantially greater binding and efficacy at MC1r than at other melanocortin receptors. We have selected one of our MC1r peptide drug candidates, designated PL-8177, as a clinical trial candidate.

1

The following chart shows the status of our drug development programs:

# **Our Strategy**

Key elements of our business strategy include:

Using our technology and expertise to develop and commercialize products in our active drug development programs; Entering into strategic alliances and partnerships with pharmaceutical companies to facilitate the development, manufacture, marketing, sale and distribution of product candidates that we are developing; Partially funding our product development programs with the cash flow generated from research collaboration and license agreements and any potential future agreements with third parties; and Completing development and seeking regulatory approval of bremelanotide for FSD and our other product candidates.

#### **Risks Related to Our Business**

Our business is subject to numerous risks and uncertainties, including those highlighted in the section of this prospectus entitled Risk Factors immediately following this prospectus summary, which you should read carefully before deciding to invest in our securities. These risks include, among others, the following:

We have incurred substantial losses since our inception and we anticipate that we will continue to incur losses for the foreseeable future. We expect to incur additional losses as we continue our development of bremelanotide for FSD, PL-3994 and other product candidates and, unless and until we receive regulatory approval under applicable regulatory requirements, we cannot sell our products and will not have product revenues from them; We are substantially dependent on the clinical and commercial success of our product candidates, primarily our lead product candidate, bremelanotide for FSD, for which we are preparing to initiate Phase 3 clinical trials; We may be unable to obtain regulatory approval for bremelanotide for FSD or future product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations; Even if bremelanotide for FSD or our other product candidates receive regulatory approval, they may fail to achieve the level of market acceptance needed for us to have commercial success; Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration and expansion;

Overview 9

We will require substantial additional funding to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts;

We have limited control over development activities in Europe for our lead product candidate, bremelanotide for FSD, including regulatory approvals, and no direct control over commercialization efforts due to an agreement with Gedeon Richter Plc, or Gedeon Richter. If Gedeon Richter fails in obtaining regulatory approval or market acceptance of bremelanotide for FSD in Europe, we may be unable to generate any revenue or business for bremelanotide for FSD in Europe;

If our efforts to protect our intellectual property related to bremelanotide for FSD or any future product candidates are not adequate, we may not be able to compete effectively in our market; and

We rely on a small management team and staff as well as various contractors and consultants to provide critical services to us, including services related to our clinical programs for bremelanotide and PL-3994 and our preclinical programs for MC1r and MC4r peptide drug candidates. Such programs could be adversely affected if we lose the services of existing key personnel.

# **Corporate Information**

We were incorporated under the laws of the State of Delaware on November 21, 1986 and commenced operations in the biopharmaceutical area in 1996. Our corporate offices are located at 4B Cedar Brook Drive, Cranbury, New Jersey 08512 and our telephone number is (609) 495-2200. Our internet address is *www.palatin.com*. The information on our website is not incorporated by reference into this prospectus and should not be considered to be part of this prospectus. Our website address is included in this prospectus as an inactive textual reference only.

Palatin Technologies, Inc. and the Palatin logo are our trademarks. All other trademarks and service marks appearing in this prospectus are the property of their respective owners.

3

## THE OFFERING

Common stock offered by us

shares plus shares of our common stock underlying the warrants offered in this offering.

Warrants offered by us

Warrants to purchase up to shares of common stock. Each warrant will have an exercise price of \$ per share, will be exercisable upon issuance and will expire five years from the date of issuance. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants. The warrants will not be listed on any national securities exchange or other nationally recognized trading system, including the NYSE MKT.

Option to purchase additional units

We have granted the underwriters a 30-day option to purchase up to additional units from us at the public offering price, less underwriting discounts and commissions, to cover over-allotments, if any.

Offering price

\$ per unit.

Common stock outstanding after this offering

shares if we sell all units being offered in this offering, or shares of our common stock if the warrants offered in this offering are issued and exercised in full.

Use of proceeds

We intend to use the proceeds from this offering to advance our Phase 3 clinical trials for bremelanotide for FSD, the clinical and preclinical development of our other product candidates and programs and working capital and general corporate purposes. See Use of Proceeds on page 33 for a more complete description of the intended use of the net proceeds from this offering.

Risk factors

You should read the section of this prospectus entitled Risk Factors beginning on page 5 and the other information included in this prospectus for a discussion of factors that you should consider before deciding to invest in our securities.

NYSE MKT symbol

#### **PTN**

The number of shares of our common stock to be outstanding after this offering is based on 39,490,161 shares outstanding as of October 21, 2014, and assumes the sale of units in this offering.

Unless otherwise indicated, all information in this prospectus, including the number of shares of our common stock to be outstanding after this offering set forth above, excludes the following:

52,829 shares of common stock reserved as of October 21, 2014 for issuance upon any conversion of our Series A Convertible Preferred Stock outstanding as of October 21, 2014;

4,229,913 shares of common stock issuable upon the exercise of stock options at exercise prices ranging from \$0.60 to \$37.50 per share outstanding as of October 21, 2014;

845,900 shares of common stock issuable upon the vesting of outstanding restricted stock units as of October 21, 2014 which vest on dates between June 25, 2015 and June 25, 2018, subject to the fulfillment of services conditions; and 91,251,531 shares of common stock issuable upon the exercise of warrants at exercise prices ranging from \$0.01 to \$1.50 per share.

Unless otherwise indicated, all information in this prospectus assumes no exercise by the underwriters of their over-allotment option.

4

THE OFFERING 11

THE OFFERING 12

## **RISK FACTORS**

Investing in our securities involves a high degree of risk. You should carefully consider the risks described below and other information included in this prospectus, including the financial statements and related notes that appear at the end of this prospectus, before deciding to invest in our securities. These risks should be considered in conjunction with any other information included herein, including in conjunction with forward-looking statements made herein. If any of the following risks actually occur, they could materially adversely affect our business, financial condition, results of operations or prospects. Additional risks and uncertainties that we do not presently know or that we currently deem immaterial may also impair our business, financial condition, results of operations and prospects.

# Risks Relating to Our Financial Results and Need for Financing

We have incurred substantial losses and 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, 2014, we had an accumulated deficit of \$274.0 million. We expect to incur additional losses as we continue our development of bremelanotide, PL-3994 and other product candidates. These losses, among other things, have had and will continue to have an adverse effect on our stockholders—equity, total assets and working capital.

Since 2005 we have not had any products available for commercial sale and we have received no revenues from the sale of our product candidates. For the foreseeable future, we will have to fund all of our operations and capital expenditures from contract revenue under collaborative development agreements, existing cash balances and outside sources of financing, which may not be available on acceptable terms, if at all. Unless and until we receive approval from the United States Food and Drug Administration, or FDA, or other equivalent regulatory authorities outside the United States, we cannot sell our products and will not have product revenues from them. We have devoted substantially all of our efforts to research and development, including preclinical and clinical trials. Because of the numerous risks associated with developing drugs, we are unable to predict the extent of future losses, whether or when any of our product candidates will become commercially available, or when we will become profitable, if at all.

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

Our operations are primarily focused on acquiring, developing and securing our proprietary technology, conducting preclinical and clinical studies and formulating and manufacturing on a small-scale basis our principal product candidates. These operations provide a limited basis for stockholders to assess our ability to commercialize our product candidates.

We have not yet demonstrated our ability to perform the functions necessary for the successful commercialization of any of our current product candidates. The successful commercialization of our product candidates will require us to perform a variety of functions, including:

continuing to conduct preclinical development and clinical trials; participating in regulatory approval processes;

RISK FACTORS 13

formulating and manufacturing products, or having third parties formulate and manufacture products;

post-approval monitoring and surveillance of our products;

conducting sales and marketing activities, either alone or with a partner; and