

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

PALATIN TECHNOLOGIES INC

Form: 8-K

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act Of 1934

Date of Report (Date of earliest event reported): September 21, 2015

Palatin Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-15543
(Commission
File Number)

95-4078884
(IRS employer
identification number)

4B Cedar Brook Drive, Cranbury, NJ
(Address of principal executive offices)

08512
(Zip Code)

Registrant's telephone number, including area code: **(609) 495-2200**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 2.02 Results of Operations and Financial Condition.

On September 21, 2015, we issued a press release including results for our third quarter and fiscal year ended June 30, 2015, and announcing a teleconference and webcast to be held September 21 at 11:00 a.m. Eastern Time, which will include a discussion on results of operations in greater detail and an update on corporate developments. We have attached a copy of the press release as an exhibit to this report.

The information in this Item 2.02 and the corresponding information in the attached Exhibit 99 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information contained in this Item 2.02 and the corresponding information in the attached Exhibit 99 shall not be incorporated into any registration statement or other document filed with the Securities and Exchange Commission by the company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

[99](#) Press Release dated September 21, 2015

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PALATIN TECHNOLOGIES, INC.

Date: September 21, 2015

By: /s/ Stephen T. Wills
Stephen T. Wills, CPA, MST
Executive Vice President, Chief Financial
Officer and Chief Operating Officer

EXHIBIT INDEX

[99](#) Press Release dated September 21, 2015

Palatin Technologies, Inc. Reports Fourth Quarter and Fiscal Year End 2015 Results

CRANBURY, NJ – September 21, 2015 – Palatin Technologies, Inc. (NYSE MKT: PTN), a biopharmaceutical company developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential, today announced results for its fourth quarter and fiscal year ended June 30, 2015.

Fiscal Year Ended June 30, 2015 and Recent Highlights

- Bremelanotide development for Female Sexual Dysfunction (FSD):

- o Palatin initiated Protocols 301 and 302 of its Phase 3 *reconnect study* in the United States and Canada for the treatment of FSD in December 2014 and January 2015, respectively. Further information on the trial protocols can be found at clinicaltrials.gov.
 - The two Phase 3 studies are progressing as planned and meeting target objectives.
 - Enrollment is greater than 50% to date and is expected to be completed in the fourth quarter of calendar year 2015.
 - Top-line data is expected to be available in the third quarter of calendar year 2016.
 - The clinical trials are designed to randomize approximately 1100 women (~550 per trial) to evaluate the efficacy and safety of subcutaneous bremelanotide in premenopausal women with hypoactive sexual desire disorder as an on-demand, as-needed treatment. For further information visit reconnectstudy.com.



- Business Development

- FSD Program

- August 2014, Palatin entered into a license agreement with Gedeon Richter (Richter) to co-develop and commercialize bremelanotide for FSD in the European Union, other European countries and additional selected countries. Palatin received €7.5 million (\$9.8 million) in total upfront payments from Richter, and a milestone payment of €2.5 million (\$3.1 million) upon the initiation of its Phase 3 clinical trial program in the United States.
 - September 2015, Palatin entered into a termination agreement pursuant to which Palatin and Richter agreed to mutually and amicably terminate the license agreement. In connection with this termination, all rights and licenses to co-develop and commercialize bremelanotide for FSD indications held by Richter have terminated and reverted back to Palatin. Neither we nor Gedeon Richter have any future material obligations under the license agreement. There are no payment or reimbursement obligations as a result of the license agreement termination.
 - Palatin now has the global rights to bremelanotide for FSD, providing the Company and its business development efforts with additional options and flexibility.
 - Palatin is actively engaged in licensing and collaboration discussions with multiple companies for both global and regional commercial rights to bremelanotide.

- o Natriuretic Peptide Program for Heart Failure (HF)

- Palatin is advancing its lead compound, PL-3994, towards a Phase 2A multiple dose study in HF patients.
 - The Company is actively engaged in licensing and collaboration discussions with multiple companies for both global and regional rights.

- o MC1r Anti-Inflammatory Program

- Palatin is advancing its lead compound, PL-8177, towards a Phase 1 clinical trial.
 - The Company is actively engaged in licensing and collaboration discussions with multiple companies for both global and regional rights.

- o MC4r Agonist Program for Obesity/Diabetes
 - The research collaboration and license agreement dated January 2007 with AstraZeneca (AZ) expired because AZ ceased developing a compound covered by the agreement. All rights and licenses that we granted to AZ were returned to Palatin upon expiration of the agreement.
 - Palatin is advancing its lead compound, PL-8905, towards a Phase 1 clinical trial.
 - The Company is actively engaged in licensing and collaboration discussions with multiple companies for both global and regional rights.

- Financing Transactions
 - o July 2015, Palatin closed on \$30 million of debt and equity financing consisting of:
 - \$10 million venture loan, which includes an interest-only payment period for the first eighteen months of a four year secured term loan.
 - \$20 million private placement of Series E warrants to purchase 21,917,808 shares of common stock and Series F warrants to purchase 2,191,781 shares of common stock.
 - o December 2014, Palatin closed on \$30 million of debt and equity financing consisting of:
 - \$10 million venture loan, which includes an interest-only payment period for the first eighteen months of a four year secured term loan.
 - \$20 million private placement of 2,050,000 shares of common stock and Series warrants to purchase 24,919,325 shares of common stock.

- Intellectual Property - Palatin obtained patents during the year:
 - o U.S. Patent 8,828,926 issued September 9, 2014, claiming uses of Palatin's PL-3994 natriuretic peptide receptor product candidate for treatment of acute asthma and chronic obstructive pulmonary disease.
 - o U.S. Patent 8,846,601 issued September 30, 2014, claiming melanocortin receptor 4 specific peptides with potential utility for treatment of obesity, metabolic syndrome, diabetes and sexual dysfunction.
 - o U.S. Patent 8,877,890 issued November 2014, claiming melanocortin receptor-1 cyclic peptides with potential application in treatment of inflammatory and dermatologic disease indications.
 - o U.S. Patent 8,933,194 issued January 13, 2015, claiming linear melanocortin receptor 1 specific peptides

- In December 2014, Palatin received \$0.5 million in net proceeds from the sale of New Jersey State net operating loss carryforwards.

Fourth Quarter and Fiscal Year Ended 2015 Results

Palatin reported a net loss of \$12.1 million, or \$(0.09) per basic and diluted share, for the quarter ended June 30, 2015, compared to a net loss of \$4.3 million, or \$(0.04) per basic and diluted share, for the same period in 2014.

-More-

The increase in net loss for the quarter ended June 30, 2015 compared to the net loss for the quarter ended June 30, 2014 was the result of an increase in operating expenses primarily related to our bremelanotide for FSD Phase 3 development program.

For the year ended June 30, 2015, Palatin reported a net loss of \$17.7 million, or \$(0.15) per basic and diluted share compared to a net loss of \$13.9 million, or \$(0.13) per basic and diluted share for the year ended June 30, 2014.

The increase in net loss for the year ended June 30, 2015, compared to the net loss for the year ended June 30, 2014 was mainly attributable to the development costs for the initiation and progression of the Phase 3 clinical trials of bremelanotide for FSD.

Revenue

For the year ended June 30, 2015, Palatin recognized \$12.9 million of license and contract revenue under the agreement with Gedeon Richter. There were no revenues recorded in the quarter ended June 30, 2015 or in the year ended June 30, 2014.

Operating Expenses

Operating expenses for the quarter ended June 30, 2015 were \$11.8 million, compared to \$4.3 million for the comparable quarter of 2014. For the year ended June 30, 2015, Palatin incurred \$30.2 million of operating expenses, compared to \$15.8 million for the year ended June 30, 2014.

The increase in operating expenses for the year and quarter ended June 30, 2015 was primarily the result of higher period costs related to Phase 3 clinical trial program costs for bremelanotide for the treatment of FSD.

Cash Position

Palatin's cash and cash equivalents were \$27.3 million as of June 30, 2015 compared to cash and cash equivalents of \$12.2 million at June 30, 2014. Current liabilities were \$7.4 million as of June 30, 2015, compared to \$1.8 million, net of \$1.0 million of deferred income, as of June 30, 2014.

Palatin believes that its existing capital resources, together with approximately \$29.7 million received from the July 2015 financings will be adequate to fund planned operations through the quarter ending September 30, 2016. Assuming the Phase 3 clinical trials of bremelanotide for FSD are successful, as to which there can be no assurance, the Company will need additional funding to complete submission of required regulatory applications to the FDA for bremelanotide for FSD.

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CONFERENCE CALL / WEBCAST

Palatin will host a conference call and webcast on September 21, 2015 at 11:00 a.m. Eastern time to discuss the results of operations and an update on corporate developments in greater detail. Individuals interested in listening to the conference call live can dial 1-888-505-4369 (domestic) or 1-719-325-2393 (international), pass code 989803. The webcast and replay can be accessed by logging on to the "Investor/Media Center-Webcasts" section of Palatin's website at <http://www.Palatin.com>.

A telephone and webcast replay will be available approximately one hour after the completion of the call. To access the telephone replay, dial 1-888-203-1112 (domestic) or 1-719-457-0820 (international), pass code 989803. The webcast and telephone replay will be available through September 28, 2015.

About Palatin Technologies, Inc.

Palatin Technologies, Inc. is a biopharmaceutical company developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential. Palatin's strategy is to develop products and then form marketing collaborations with industry leaders in order to maximize their commercial potential. For additional information regarding Palatin, please visit Palatin's website at www.Palatin.com.

Forward-looking Statements

Statements in this press release that are not historical facts, including statements about future expectations of Palatin Technologies, Inc., such as statements about clinical trial results, potential actions by regulatory agencies including the FDA, regulatory plans, development programs, business development and licensing programs, proposed indications for product candidates and market potential for product candidates, are "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. Palatin intends that such forward-looking statements be subject to the safe harbors created thereby. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that could cause Palatin's actual results to be materially different from its historical results or from any results expressed or implied by such forward-looking statements. Palatin's actual results may differ materially from those discussed in the forward-looking statements for reasons including, but not limited to, results of clinical trials, regulatory actions by the FDA and the need for regulatory approvals, Palatin's ability to fund development of its technology and establish and successfully complete clinical trials, the length of time and cost required to complete clinical trials and submit applications for regulatory approvals, entering into marketing and distribution agreements, products developed by competing pharmaceutical, biopharmaceutical and biotechnology companies, commercial acceptance of Palatin's products, and other factors discussed in Palatin's periodic filings with the Securities and Exchange Commission. Palatin is not responsible for updating for events that occur after the date of this press release.

Palatin Technologies Investor Inquiries:

Stephen T. Wills, CPA,
MST
Chief Operating Officer / Chief Financial Officer
Tel: (609) 495-2200 / info@Palatin.com

Palatin Technologies Media Inquiries:

Paul Arndt, MBA, LifeSci Advisors, LLC

Managing Director
Tel: (646) 597-6992 / Paul@LifeSciAdvisors.com

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(Financial Statement Data Follows)

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Statements of Operations

	Year Ended June 30,		
	2015	2014	2013
REVENUES:			
License and contract	\$ 12,951,730	\$ -	\$ 10,361
OPERATING EXPENSES:			
Research and development	24,560,233	10,826,921	10,528,691
General and administrative	5,677,654	4,960,731	5,066,830
Total operating expenses	<u>30,237,887</u>	<u>15,787,652</u>	<u>15,595,521</u>
Loss from operations	<u>(17,286,157)</u>	<u>(15,787,652)</u>	<u>(15,585,160)</u>
OTHER INCOME (EXPENSE):			
Investment income	35,439	18,923	42,734
Interest expense	(661,697)	(6,211)	(8,411)
Foreign exchange transaction loss	(284,656)	-	-
Increase in fair value of warrants	-	-	(7,069,165)
Gain on disposition of supplies and equipment	-	-	4,620
Total other income (expense), net	<u>(910,914)</u>	<u>12,712</u>	<u>(7,030,222)</u>
Loss before income taxes	(18,197,071)	(15,774,940)	(22,615,382)
Income tax benefit	531,508	1,846,646	1,753,208
NET LOSS	<u>\$ (17,665,563)</u>	<u>\$ (13,928,294)</u>	<u>\$ (20,862,174)</u>
Basic and diluted net loss per common share	<u>\$ (0.15)</u>	<u>\$ (0.13)</u>	<u>\$ (0.21)</u>
Weighted average number of common shares outstanding used in computing basic and diluted net loss per common share	<u>121,014,506</u>	<u>106,679,476</u>	<u>97,618,714</u>

PALATIN TECHNOLOGIES, INC.
and Subsidiary
Consolidated Balance Sheets

	<u>June 30, 2015</u>	<u>June 30, 2014</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 27,299,268	\$ 12,184,605
Prepaid expenses and other current assets	1,896,747	156,393
Total current assets	29,196,015	12,340,998
Property and equipment, net	123,158	160,748
Other assets	155,279	57,308
Total assets	\$ 29,474,452	\$ 12,559,054
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,106,484	\$ 261,280
Accrued expenses	6,223,483	1,508,958
Capital lease obligations	25,871	-
Unearned revenue	-	1,000,000
Total current liabilities	7,355,838	2,770,238
Notes payable, net of discount	9,781,086	-
Capital lease obligations	41,749	-
Other non-current liabilities	91,304	-
Total liabilities	17,269,977	2,770,238
Stockholders' equity:		
Preferred stock of \$0.01 par value – authorized 10,000,000 shares; Series A Convertible; issued and outstanding 4,697 shares as of June 30, 2015 and 2014, respectively	47	47
Common stock of \$0.01 par value – authorized 300,000,000 shares; issued and outstanding 57,128,433 shares as of June 30, 2015 and 39,416,595 as of June 30, 2014, respectively	571,284	394,166
Additional paid-in capital	303,332,460	283,428,356
Accumulated deficit	(291,699,316)	(274,033,753)
Total stockholders' equity	12,204,475	9,788,816
Total liabilities and stockholders' equity	\$ 29,474,452	\$ 12,559,054