

PALATIN TECHNOLOGIES INC

Form 8-K

November 13, 2018

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): November 13, 2018

Palatin Technologies, Inc.

(Exact name of registrant as specified in its charter)

Delaware 001-15543 95-4078884
(State or other jurisdiction (Commission (IRS employer
of incorporation) File Number) identification number)

4B Cedar Brook Drive, Cranbury, NJ 08512
(Address of principal executive offices) (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))

Emerging growth company

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On November 13, 2018, we issued a press release including results for our first quarter ended September 30, 2018 and announcing a teleconference and webcast to be held November 13, 2018 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 99.1 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 99.1 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 7.01. Regulation FD Disclosure.

AMAG Pharmaceuticals, Inc. (“AMAG”), Palatin Technologies, Inc.’s (“Palatin”) exclusive North American licensee of Vyleesi™ (bremelanotide), has been in discussions with the U.S. Food and Drug Administration (the “FDA”) regarding its review of the New Drug Application (“NDA”) submission for Vyleesi. The FDA has requested that additional data be generated from a small Phase 1 study with premenopausal volunteers assessing 24-hour ambulatory blood pressure with short term daily use of Vyleesi. As part of its ongoing review, the FDA has indicated that these data are required to help characterize the impact of frequent dosing, including to help inform the Vyleesi label. Palatin and AMAG believes that this study can be conducted and data submitted prior to March 23, 2019, the currently scheduled Prescription Drug User Fee Act (“PDUFA”) date. The FDA will assess the need for an Advisory Committee meeting after receipt and review of the requested data, and has informed AMAG that the previously communicated January 2019 Advisory Committee meeting will not take place. Although AMAG’s discussions to date with the FDA are preliminary, and AMAG will continue to have further discussions with the FDA on this matter, AMAG believes that this submission of additional data could cause a delay of the potential approval of Vyleesi by three to six months.

This report 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. Any statements contained herein or therein which do not describe historical facts, including, among others, expectations as to the FDA’s requests; beliefs that the additional study can be conducted and data submitted prior to the PDUFA date; the impact on the timeline of the potential approval of Vyleesi; and expectations as to further discussions with the FDA are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements.

Such risks and uncertainties include, among others, the risk that the FDA will require additional or more comprehensive study data, or issue a complete response letter, which could cause a further delay or challenges to the approval of the Vyleesi NDA, or which could result in unanticipated restrictions or warnings on the product label, if approved, and the risk that the costs associated with such efforts will be higher than anticipated, as well as those risks identified in Palatin’s filings with the U.S. Securities and Exchange Commission (the “Commission”), including its Annual Report on Form 10-K for the year ended June 30, 2018 and subsequent filings with the Commission, including its Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, which are available at the Commission’s website at www.sec.gov. Any such risks and uncertainties could materially and adversely affect Palatin’s results of operations, its profitability and its cash flows, which would, in turn, have a significant and adverse impact on Palatin’s stock price. Palatin cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Palatin disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or

that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

99.1

Press Release dated November 13, 2018

2

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: November 13, 2018 By: /s/ Stephen T. Wills
Stephen T. Wills, CPA, MST
Executive Vice President, Chief Financial Officer and Chief Operating Officer

EXHIBIT INDEX

99.1

Press Release dated November 13, 2018

4