PALATIN TECHNOLOGIES INC
Form 8-K
January 07, 2019

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): January 7, 2019

Palatin Technologies, Inc.
(Exact name of registrant as specified in its charter)

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

(Former name or former address, if changed since last report)
Not Applicable

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securites Exchange Act of 1934 (§240.12b-2 of this chapter).

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 7.01. Regulation FD Disclosure.

AMAG Pharmaceuticals, Inc. ("AMAG"), Palatin Technologies, Inc.'s ("Palatin") exclusive North American licensee of Vyleesi™ (bremelanotide), provided an update today on the regulatory development of Vyleesi, including noting that the U.S. Food and Drug Administration (the "FDA") has extended the Prescription Drug User Fee Act ("PDUFA") date for by three months to June 23, 2019.

An FDA-requested frequent-dosing study with premenopausal volunteers assessing short term daily use of Vyleesi has been initiated. Study results are anticipated to be submitted to the FDA prior to the updated PDUFA date of June 23, 2019.

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.

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: January 7, 2019 By: /s/ Stephen T. Wills
Stephen T. Wills, CPA, MST
Executive Vice President, Chief Financial Officer and Chief Operating Officer