

PALATIN TECHNOLOGIES INC
Form 8-K
February 03, 2017

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): February 2, 2017
Palatin Technologies, Inc.
(Exact name of registrant as specified in its charter)

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

| | |
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| 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:

- 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))

Item 8.01. Other Events

As previously disclosed, on January 8, 2017, Palatin Technologies, Inc. (“Palatin”) and AMAG Pharmaceuticals, Inc. (“AMAG”) entered into a licensing agreement (the “License Agreement”) in which Palatin granted AMAG exclusive North American rights to develop and commercialize Rekynda™ (bremelanotide), an investigational product designed for on-demand treatment of hypoactive sexual desire disorder (“HSDD”) in pre-menopausal women (the “Licensing Transaction”). Following the satisfaction of the conditions to closing under the License Agreement, the Licensing Transaction closed on February 2, 2017 (the “Effective Date”).

Under the terms of the License Agreement, Palatin has granted AMAG (i) an exclusive license in all countries of North America (the “Territory”), with the right to grant sub-licenses, to research, develop and commercialize products containing bremelanotide (the “Products”), (ii) a non-exclusive license in the Territory, with the right to grant sub-licenses, to manufacture Products, and (iii) a non-exclusive license in all countries outside the Territory, with the right to grant sub-licenses, to research, develop and manufacture (but not commercialize) the Products.

Pursuant to the terms of and subject to the conditions in the License Agreement, AMAG is required to make the following payments to Palatin: (i) \$60 million as a one-time upfront payment within five days following the Effective Date (the “Upfront Consideration”) and (ii) up to an aggregate amount of \$25 million to reimburse Palatin for all reasonable, documented, out-of-pocket expenses incurred by Palatin, following the Effective Date, in connection with the development and regulatory activities necessary to file a new drug application (“NDA”) for a Product for HSDD in the United States. Palatin has received the \$60 million upfront payment from AMAG.

In addition, pursuant to the terms of and subject to the conditions in the License Agreement, Palatin will be eligible to receive from AMAG: (i) up to \$80 million in specified regulatory payments upon achievement of certain regulatory milestones, and (ii) up to \$300 million in sales milestone payments based on achievement of annual net sales amounts for all Products in the Territory.

AMAG is also obligated to pay Palatin tiered royalties on annual net sales of Products, on a product-by-product basis, in the Territory ranging from the high single-digits to the low double-digits. The royalties will expire on a product-by-product and country-by-country basis upon the latest to occur of (i) the earliest date on which there are no valid claims of Palatin patent rights covering such Product in such country, (ii) the expiration of the regulatory exclusivity period for such Product in such country and (iii) ten years following the first commercial sale of such Product in such country. Such royalties are subject to reduction in the event that: (a) AMAG must license additional third party intellectual property in order to develop, manufacture or commercialize a Product or (b) generic competition occurs with respect to a Product in a given country, subject to an aggregate cap on such deductions of royalties otherwise payable to Palatin. After the expiration of the applicable royalties for any Product in a given country, the license for such Product in such country would become a fully paid-up, royalty-free, perpetual and irrevocable license.

AMAG and Palatin have made customary representations and warranties and have agreed to certain customary covenants, including confidentiality and indemnification.

Rekynda is currently in clinical development and, pursuant to the terms of the License Agreement, Palatin will continue to conduct the clinical activities to support the NDA filing that AMAG will submit, subject to reimbursement as described above. Under the License Agreement, AMAG is assuming the obligations under manufacturing and supply agreements with Catalent Belgium S.A. AMAG is not acquiring any physical assets at closing, but may acquire remaining inventories of compounds and product from Palatin when development is completed.

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The License Agreement expires on the date of expiration of all royalty obligations due thereunder unless earlier terminated in accordance with the License Agreement. AMAG has the right to terminate the License Agreement without cause, in its entirety or on a product-by-product and country-by-country basis upon at least 180 days' prior written notice to Palatin. Either party may terminate the License Agreement for cause if the other party materially breaches or defaults in the performance of its obligations, and, if curable, such material breach remains uncured for 90 days.

The foregoing is only a summary of the material terms of the License Agreement and does not purport to be a complete description of the rights and obligations of the parties under such agreement. The foregoing summary is qualified in its entirety by reference to the License Agreement, a redacted copy of which will be filed with Palatin's Quarterly Report on Form 10-Q for the quarter ended December 31, 2016.

On February 3, 2017, the Company issued a press release announcing the closing of the License Transaction, the receipt of \$60 million upfront payment from AMAG, and announcing a teleconference and webcast to be held February 9, 2017 at 11:00 a.m. Eastern time, which will include a discussion on Palatin's role in further development and regulatory approval of Rekynda. A copy of the press release is filed with this Form 8-K and is attached hereto as Exhibit 99.1.

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Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press release, dated February 3, 2017.

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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: February 3, 2017 By: /s/ Stephen T. Wills
Stephen T. Wills, CPA, MST
Executive Vice President, Chief Financial
Officer and Chief Operating Officer

EXHIBIT INDEX

Exhibit No. Description

99.1 Press release, dated February 3, 2017.

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