

PALATIN TECHNOLOGIES INC
Form 8-K
June 23, 2016

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): June 20, 2016

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))

Item 1.01 Entry into a Material Definitive Agreement

On June 20, 2016 (the “Execution Date”), Palatin Technologies, Inc. (“Palatin”) entered into a Commercial Supply Agreement (the “Agreement”) with Catalent Belgium S.A. (“Catalent”), a subsidiary of Catalent Pharma Solutions, Inc., with an effective date of June 10, 2016. Pursuant to the Agreement, Palatin engaged Catalent to manufacture drug product and prefilled syringes, assemble prefilled syringes into an auto-injector device, and package and label the combination product (such final combination product, the “Product”). Palatin intends to engage third parties to provide Catalent with a supply of bremelanotide and the disposable auto-injector device.

Catalent will have the right to supply at least 80% of Palatin’s needs for the Product during the term of the Agreement. Palatin entered into the Agreement in anticipation of approval by the U.S. Food and Drug Administration (the “FDA”) of the Product. All patients are projected to complete Phase 3 clinical trials of bremelanotide for hypoactive sexual desire disorder, a type of female sexual dysfunction, by the third quarter of calendar year 2016. The Agreement also includes customary terms and conditions relating to forecasting and minimum commitments, ordering, delivery, inspection and acceptance, among other matters.

The initial term of the Agreement will continue for a period of five years after the date that is 60 days from the date on which the FDA gives market regulatory approval of the Product, unless earlier terminated in accordance with the terms of the Agreement. The initial term of the Agreement will be automatically extended for one 24-month period unless either party notifies the other of its desire to terminate as of the end of the initial term as outlined in the Agreement.

The Agreement may be terminated immediately by either party if the other party files a petition in bankruptcy, enters into an agreement with its creditors or similar action, or if the other party materially breaches any of the provisions of the Agreement and such breach is not cured within the period outlined in the Agreement. Catalent may terminate the Agreement if Palatin fails to obtain regulatory approval of the Product. Palatin may terminate the Agreement if Catalent fails to supply products in accordance with the Agreement, or if Palatin provides notice and pays a termination penalty.

On the Execution Date, Palatin and Catalent also entered into a Manufacturing Preparation and Services Agreement (the “Manufacturing Agreement”), pursuant to which Catalent agreed to supplement its manufacturing capacity and infrastructure to provide certain services in relation to the manufacture of the Product and to reserve certain manufacturing capacity at the relevant facility. The Manufacturing Agreement continues until the completion of each party’s obligations or until such other date as the parties may mutually agree in writing.

The Manufacturing Agreement may be terminated immediately by either party if the other party files a petition in bankruptcy, enters into an agreement with its creditors or similar action, or if the other party materially breaches any of the provisions of the Manufacturing Agreement and such breach is not cured within the period outlined in the Manufacturing Agreement. The Manufacturing Agreement may also be terminated by Palatin at any time upon 30 days’ prior written notice, provided, however, that in the event of such termination, Palatin’s payment obligations under the Manufacturing Agreement will be accelerated, and Palatin will owe Catalent an additional fee.

The foregoing is only a summary of the material terms of the Agreement and the Manufacturing Agreement, does not purport to be a complete description of the rights and obligations of the parties under either agreement, and is qualified in its entirety by reference to each agreement that Palatin expects to file as an exhibit to its Annual Report on Form 10-K for the fiscal year ending June 30, 2016.

Forward-looking Statements

There can be no assurance that results of Phase 3 clinical trials will support approval of the Product, or that the FDA will approve marketing the Product. Statements in this report that are not historical facts, including statements about future expectations of Palatin, such as statements about clinical trial results, potential actions by regulatory agencies including the FDA, regulatory plans, development programs, proposed indications for the Product and other product candidates and market potential for the Product and other 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, 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 report.

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: June 23, 2016 By: /s/ Stephen T. Wills

Stephen T. Wills, CPA, MST

Executive Vice President, Chief Financial Officer and Chief Operating Officer