PROGENICS PHARMACEUTICALS INC
Form 8-K
May 11, 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) **May 10, 2018**

Progenics Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**000-23143**	**13-3379479**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

One World Trade Center, New York, New York	**10007**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(646) 975-2500**

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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company

If an emerging growth company, indicate by check mark 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 1.01. Entry Into a Material Definitive Agreement.

On May 10, 2018, Progenics Pharmaceuticals, Inc. ("Progenics"), Valeant Pharmaceuticals International, Inc. ("Valeant"), Salix Pharmaceuticals, Inc. ("Salix"), Wyeth LLC ("Wyeth" and, together with Progenics, Valeant and Salix, each "Plaintiff" and collectively "Plaintiffs") and Par Sterile Products, LLC ("Par Sterile") and Par Pharmaceutical, Inc. ("Par Pharmaceutical" and, together with Par Sterile, "Par") entered into a Settlement and License Agreement (the "Agreement") relating to an action for patent infringement in the U.S. District Court for the District of New Jersey (the "District Court"), Civil Action No. 17-06449-SRC-CLW, brought by Plaintiffs against Par (the "District Court Case"). In the suit, Progenics and the other Plaintiffs allege that a generic methylnaltrexone bromide injection for subcutaneous use (the "Par Products") for which Par is seeking approval to market in the U.S. pursuant to an Abbreviated New Drug Application ("ANDA") filing with the U.S. Food and Drug Administration (the "FDA") infringes two U.S. patents owned by Progenics as well as other patents separately owned by each of the other Plaintiffs (the "Patents-In-Suit"). The following is a summary of the material terms of the Agreement.

The Agreement provides for a full settlement and release by both Plaintiffs and Par of all claims that were or could have been asserted in the District Court Case and all resulting damages or other remedies. Plaintiffs and Par have agreed to file a Stipulated Consent Judgment and Injunction within five business days after the execution of the Agreement. Plaintiffs and Par have further acknowledged and agreed that the 30-month stay imposed by the FDA in relation to the approval of Par's ANDA for the Par Products (the "Par ANDA") should be terminated.

In the Agreement, Par admits that each of the Patents-In-Suit is a valid and enforceable U.S. patent as applied to the Par Products and the Par ANDA and that one or more of the Patents-In-Suit would be infringed by the Par Products and the Par ANDA. In connection with the Par Products and Par ANDA, Par has further agreed not to contest the patentability, validity or enforceability of the Patents-In-Suit in the U.S. or take any action intended to adversely affect Plaintiffs' rights in and to the Patents-In-Suit.

Under the Agreement, Plaintiffs grant Par a non-exclusive, royalty-free, non-transferable, non-sublicensable, limited license under the Patents-In-Suit to make, import, and sell the Par Products in the U.S., or make outside the U.S. solely for importation into the U.S. (the "License") beginning on the earliest of (i) September 30, 2030; (ii) for either of the Par Products, one hundred eighty-one (181) days after any third party who is the "First Applicant" (as defined in 21. U.S.C. § 355(j)(5)(B)(iv)(II)) markets a single-dose vial or pre-filled syringe that has been FDA approved or submitted for approval under an ANDA as a generic version of RELISTOR® Injection for subcutaneous use (the "Generic Products"); (iii) for either of the Par Products, the date on which a non-First Applicant third party markets an authorized generic (under the RELISTOR® New Drug Application ("NDA") but without the RELISTOR® trademark) single-dose vial or pre-filled syringe of methylnaltrexone bromide for subcutaneous use in the U.S.; (iv) for either of the Par Products, the date on which a third party who is not a First Applicant (or who is a First Applicant who has forfeited or otherwise waived its 180-day exclusivity) markets or is first authorized by Plaintiffs to market the Generic Products in the U.S.; (v) the date on which a final court decision is entered holding that each of the asserted claims against Par in the District Court Case from the Patents-In-Suit are invalid and/or unenforceable, or not infringed by the single-dose vial Par Product; or (vi) the date on which the Patents-In-Suit have expired, been permanently abandoned

or delisted from the FDA's Orange Book. Plaintiffs have also granted to Par a limited pre-commercialization license to manufacture and/or import the Par Products into the U.S. starting one hundred fifty (150) days prior to the effective date of the License solely to the extent reasonably necessary to enable Par to market the Par Products in the U.S. on or after the effective date of the License.

Under the Agreement, Plaintiffs agree not to (i) file any submissions with any governmental agencies that would interfere with Par's efforts to obtain FDA approval of the Par ANDA or market the Par Products under the terms of the Agreement, or (ii) discontinue RELISTOR® Injection prior to the expiration of the licensed patents for reasons other than safety or efficacy. Plaintiffs have also agreed to notify Par if they grant any license under the Patents-in-Suit to a non-First Applicant third party with terms more favorable than those provided to Par under the Agreement with respect to the effective date of the License and pre-commercialization rights, in which case the Agreement shall be automatically amended to include the more favorable terms. Plaintiffs have also granted Par a waiver of any regulatory exclusivities concerning RELISTOR® Injection that may prevent approval of the Par ANDA. In addition, Plaintiffs have agreed to submit, within five business days of Par's request, appropriate and reasonable documentation to the FDA evidencing the licenses, covenant not to sue and waivers set forth in the Agreement.

The foregoing summary of the Agreement does not purport to be complete and is qualified in its entirety by reference to the text thereof, which is attached as Exhibit 10.1 hereto and incorporated in this Item 1.01 by reference.

Safe Harbor

This filing contains forward-looking statements regarding the anticipated results of the settlement with Par. There are many important factors that could cause actual results to differ materially from those in these forward-looking statements. These factors include the following: that the U.S. District Court does not approve the Stipulated Consent Judgment and Injunction or that public or private plaintiffs challenge the enforceability of the Agreement whether or not additional third parties may seek to market generic versions of RELISTOR® Injection by filing ANDAs with the FDA and the results of any litigation that we file to defend and/or assert our patents against such companies the ability of our third party manufacturers to manufacture sufficient quantities of RELISTOR® Injection in accordance with Good Manufacturing Practices and other requirements of the regulatory approvals for RELISTOR® Injection and at an acceptable cost our ability to protect the proprietary technologies and intellectual property related to RELISTOR® Injection and to secure and maintain additional intellectual property protection for RELISTOR® Injection and a variety of other risks common to our industry. Additional factors that could cause actual results to differ materially from those projected or suggested in any forward-looking statements are contained in Progenics' recent annual and quarterly reports filed with the Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" in such filings, which are incorporated in this filing by this reference.

Forward-looking statements speak only as of the date of this filing, and Progenics undertakes no obligation to update or revise these statements.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*

Exhibit No.	Description
10.1	Settlement and License Agreement by and among Progenics Pharmaceuticals, Inc., Valeant Pharmaceuticals International, Inc., Salix Pharmaceuticals, Inc., Wyeth LLC, and Par Sterile Products, LLC and Par Pharmaceutical, Inc., dated May 10, 2018.

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.

PROGENICS PHARMACEUTICALS, INC.

By: **/s/ Patrick Fabbio**
Patrick Fabbio
Senior Vice President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: May 11, 2018