PROGENICS PHARMACEUTICALS INC
Form 8-K
October 13, 2015
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) October 7, 2015

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.)
	777 Old Saw Mill River Road, Tarrytown, New York	10591
	(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (914) 789-2800

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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01. Other Events.

On October 7, 2015 Progenics Pharmaceuticals, Inc. ("Progenics") received notification of a Paragraph IV certification for certain patents for RELISTOR® (methylnaltrexone bromide) subcutaneous injection, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. The certification resulted from the filing by Mylan Pharmaceuticals, Inc. of an Abbreviated New Drug Application (ANDA) challenging such patents for RELISTOR subcutaneous injection.

Progenics and its licensee for RELISTOR, Salix Pharmaceuticals, Inc. (a wholly-owned subsidiary of Valeant Pharmaceuticals International, Inc.) are assessing the notification and intend to vigorously enforce RELISTOR intellectual property rights.

In accordance with the Hatch-Waxman Act, Progenics and Valeant have 45 days after effective notice of the Paragraph IV certification to file suit against the ANDA filer in order to obtain an automatic stay of FDA approval of the ANDA until the earlier of (i) 30 months from receipt of the notice or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed.

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/ ANGELO W. LOVALLO, JR.
Angelo W. Lovallo, Jr.
Vice President - Finance & Treasurer
(Principal Financial and Accounting Officer)

Date: October 13, 2015