PROGENICS PHARMACEUTICALS INC
Form 8-K
May 07, 2009

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 7, 2009

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.

Today, Progenics reported key results, shown below, from the open-label portion of the pivotal phase 3 clinical study of subcutaneous RELISTOR in 303 chronic, non-cancer pain patients for the treatment of opioid-induced constipation (OIC).

Data from the blinded portion of this study is scheduled to be presented tomorrow at the annual meeting of the American Pain Society (APS). Today, Wyeth and Progenics issued a press release with respect to the data scheduled to be presented from the double-blind portion of this study: "Phase 3 Clinical Study of RELISTOR Presented at American Pain Society Meeting Showed Positive Activity For the Treatment of Opioid-Induced Constipation in Chronic, Non-cancer Pain Patients." (A copy of the release can be found at www.progenics.com).

Preliminary results of open-label portion of the pivotal phase 3 study of RELISTOR in chronic, non-cancer pain patients

Patients who completed the four-week, double-blind, placebo-controlled portion of the trial were eligible to continue in the subsequent eight-week, open-label portion. During the open-label portion, patients were permitted to take RELISTOR on an as-needed basis, but no more than once daily. Of the 460 chronic, non-cancer pain patients who participated in the blinded portion of the study, 364 entered into the open-label portion of the study. Of these, 303 patients completed the open-label portion of the study. An inclusion criterion of the study was that patients had <3 rescue-free bowel movements (RFBMs) per week during the baseline screening period.

The preliminary top-line results from the eight-week, open-label period were as follows:

- Patients chose to self-administer RELISTOR on average 4.5 times per week throughout the open-label period.
    - The percentage of patients with ≥3 RFBMs per week was 59.8% over the open-label period.
- During the double-blind portion of the study, the percentage of patients with ≥3 RFBMs per week was 38.3% while on placebo compared to 58.7% and 45.3% while receiving RELISTOR daily or every other day, respectively.
- On average, the percent of injections resulting in any RFBM within four hours during the open-label portion was 34.4%.
    - This result was similar to that observed in the active treatment groups in the double-blind portion.

Consistent with the double-blind portion of the study and previous studies, RELISTOR was generally well tolerated. The most common adverse events reported in the open-label portion of the study were abdominal pain, nausea, urinary tract infection, diarrhea, and hyperhidrosis.

Results from this phase 3 study would be included in a planned supplemental New Drug Application to the U.S. Food and Drug Administration, and if approved, would add a new indication for RELISTOR for chronic pain patients with OIC in the United States. Currently, RELISTOR is approved for the treatment of OIC in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient.

Special Note Regarding Forward-Looking Statements

This document contains statements that do not relate strictly to historical fact, any of which may be forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. When we use the words “anticipates,” “plans,” “expects” and similar expressions, we are identifying forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. While it is impossible to identify or predict all such matters, these differences may result from, among other things, the inherent uncertainty of the timing and success of, and expense associated with, research, development, regulatory approval and commercialization of our products and product candidates, including the risks that clinical trials will not commence or proceed as planned; products appearing promising in early trials will not demonstrate efficacy or safety in larger-scale trials; clinical trial data on our products and product candidates will be unfavorable; our products will not receive marketing approval from regulators or, if approved, do not gain sufficient market acceptance to justify development and commercialization costs; we, our collaborators or others might identify side effects after the product is on the market; or efficacy or safety concerns regarding marketed products, whether or not originating from subsequent testing or other activities by us, governmental regulators, other entities or organizations or otherwise, and whether or not scientifically justified, may lead to product recalls, withdrawals of marketing approval, reformulation of the product, additional pre-clinical testing or clinical trials, changes in labeling of the product, the need for additional marketing applications, declining sales or other adverse events.

We are also subject to risks and uncertainties associated with the actions of our corporate, academic and other collaborators and government regulatory agencies, including risks from market forces and trends, such as those relating to the recently-announced acquisition of our RELISTOR® collaborator, Wyeth Pharmaceuticals, by Pfizer Inc.; potential product liability; intellectual property, litigation, environmental and other risks; the risk that licenses to intellectual property may be terminated for our failure to satisfy performance milestones; the risk of difficulties in, and regulatory compliance relating to, manufacturing products; and the uncertainty of our future profitability.

Risks and uncertainties also include general economic conditions, including interest- and currency exchange-rate fluctuations and the availability of capital; changes in generally accepted accounting principles; the impact of legislation and regulatory compliance; the highly regulated nature of our business, including government cost-containment initiatives and restrictions on third-party payments for our products; trade buying patterns; the competitive climate of our industry; and other factors set forth in this document and other reports filed with the U.S. Securities and Exchange Commission (SEC). In particular, we cannot assure you that RELISTOR will be commercially successful or be approved in the future in other formulations, indications or jurisdictions, or that any of our other programs will result in a commercial product.

We do not have a policy of updating or revising forward-looking statements, and we assume no obligation to update any statements as a result of new information or future events or developments. It should not be assumed that our silence over time means that actual events are bearing out as expressed or implied in 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.

PROGENICS PHARMACEUTICALS, INC.
By: /s/ ROBERT A. MCKINNEY
Robert A. McKinney
Chief Financial Officer, Senior Vice President,
Finance & Operations and Treasurer

Date: May 7, 2009