

PROGENICS PHARMACEUTICALS INC
Form 8-K
October 01, 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) October 1, 2009

Progenics Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other
jurisdiction
of incorporation)

000-23143
(Commission
File Number)

13-3379479
(IRS Employer
Identification No.)

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

10591
(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):

- 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))
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Item 8.01. Other Events.

Progenics Pharmaceuticals, Inc. (Nasdaq: PGNX) has been informed by Wyeth Pharmaceuticals, a division of Wyeth (NYSE: WYE), with which Progenics collaborates in the development and commercialization of RELISTOR®, that it has completed enrollment in a phase 3 one-year, open-label safety study of subcutaneous RELISTOR in over 1,000 chronic, non-cancer pain patients. The study enrolled ahead of anticipated schedule.

This study, initiated in December 2008, is designed to support planned supplemental regulatory filings in the U.S., Europe and elsewhere for approval of RELISTOR to treat opioid-induced constipation in the chronic-pain setting, an additional indication beyond than that for which the drug is currently approved.

In December 2008, Progenics and Wyeth initiated this safety study in accordance with U.S. Food and Drug Administration International Conference on Harmonization (ICH) Guidance, available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM129517.pdf>.

Progenics and Wyeth expect to present a consolidated safety database from this study and a 470-patient efficacy study in chronic, non-cancer pain patients, the results of which were announced in May, as part of supplemental regulatory filings which are planned for by the end of 2010.

RELISTOR is currently approved over 30 countries for the treatment of OIC in patients with advanced illness receiving palliative care.

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: October 1, 2009