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PROGENICS PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

Filed 01/26/11 for the Period Ending 01/25/11

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Telephone	9147892800
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SIC Code	2834 - Pharmaceutical Preparations
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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) **January 25, 2011**

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):

- ☐ 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 8.01. Other Events.

On January 25, 2011, Pfizer Inc. (NYSE:PFE) and Progenics Pharmaceuticals, Inc. (NASDAQ: PGNX) issued a press release alerting United States patients and physicians to a U.S. market recall of alcohol prep pads manufactured by the Triad Group, which are packaged for use with the kit presentation of RELISTOR ® (methylnaltrexone bromide) Subcutaneous Injection in the U.S.

A copy of the press release is included in this Report as Exhibit 99.1 and the information contained therein is incorporated into this Item 8.01 by this reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release dated January 25, 2011.

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: January 26, 2011

For immediate release:
January 25, 2011

Pfizer Contact:
Rick Chambers
(269) 833-6387

Progenics Contact:
Amy Martini
(914) 789-2816

Pfizer Inc. And Progenics Alert Physicians And Patients To Information Related To Triad Group Alcohol Prep Products Included In U.S. RELISTOR Kit Packaging

NEW YORK, N.Y. and TARRYTOWN, N.Y. – Pfizer Inc. and Progenics Pharmaceuticals, Inc. have learned of a United States market recall of alcohol prep pads and swabs manufactured by the Triad Group. In the interest of patient safety, Pfizer and Progenics are alerting U.S. patients and physicians to Triad's recall. Triad ® Alcohol Prep Pads are packaged for use with the kit presentation of RELISTOR ® (methylnaltrexone bromide) Subcutaneous Injection in the U.S. The RELISTOR vial and other components of the kit are not affected by the defective Triad alcohol pad. RELISTOR sold in single vials also is unaffected by this recall.

Pfizer and Progenics advise patients using the RELISTOR kit not to use the Triad alcohol prep pads included in the RELISTOR packaging for 1 X 7 kits and 1 X 2 starter kits. When preparing to take their RELISTOR injection, patients should use an alcohol prep pad from a company other than Triad, or use a sterile gauze pad with isopropyl alcohol.

Shipments of RELISTOR kits have been suspended until the alcohol pads can be replaced, which will be done as quickly as possible to enable patients to continue to receive RELISTOR. Triad alcohol prep products are not included in RELISTOR sold as single vials or in RELISTOR kits outside of the United States or with other Pfizer medications.

The following information about the recall of Triad alcohol prep products is available on the U.S. Food and Drug Administration's web site: Triad press release: http://www.fda.gov/Safety/Recalls/ucm239219.htm Safety information: http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm239319.htm .

Patients with questions about RELISTOR should consult their pharmacist or healthcare provider, or call Pfizer Medical Information at 1-800-438-1985. RELISTOR is manufactured and marketed by Pfizer under a licensing agreement with Progenics.

About RELISTOR

RELISTOR Subcutaneous Injection is approved in the United States for the treatment of opioid-induced constipation (OIC) in patients with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient. The use of RELISTOR beyond four months has not been studied. The drug is also approved for use in over 50 countries worldwide, including in the European Union, Canada, Australia and Brazil. Applications in additional countries are pending. In the 27 member states of the E.U., as well as Iceland, Norway and Liechtenstein, RELISTOR is approved for the treatment of OIC in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. In Canada, the drug is approved for the treatment of opioid-induced constipation in patients with advanced illness, receiving palliative care. When response to laxatives has been insufficient, RELISTOR should be used as an adjunct therapy to induce a prompt bowel movement. RELISTOR is the brand name under which methylnaltrexone is marketed outside Japan by Wyeth, a wholly-owned subsidiary of Pfizer.

Important Safety Information for RELISTOR

- RELISTOR is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction
- If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their physician
- Rare cases of gastrointestinal (GI) perforation have been reported in advanced illness patients. Use RELISTOR with caution in patients with known or suspected lesions of the GI tract
- Use of RELISTOR has not been studied in patients with peritoneal catheters
- The most common adverse reactions reported with RELISTOR compared with placebo in clinical trials were abdominal pain (28.5% vs. 9.8%), flatulence (13.3% vs. 5.7%), nausea (11.5% vs. 4.9%), dizziness (7.3% vs. 2.4%), diarrhea (5.5% vs. 2.4%), and hyperhidrosis (6.7% vs. 6.5%)
- Safety and efficacy of RELISTOR have not been established in pediatric patients

RELISTOR full Prescribing Information for the U.S. is available at www.relistor.com .
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