

# PROGENICS PHARMACEUTICALS INC

## FORM 8-K (Current report filing)

Filed 10/25/2006 For Period Ending 10/25/2006

Address	777 OLD SAW MILL RIVER ROAD TARRYTOWN, New York 10591
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Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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**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 25, 2006

**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 7.01. Regulation FD Disclosure**

Progenics Pharmaceuticals, Inc. today announced that it has earned a \$5 million payment from Wyeth Pharmaceuticals, a division of Wyeth . This first milestone payment under the companies' collaborative agreement was triggered by Progenics' start of a phase 3 clinical trial of intravenous methylnaltrexone for the treatment of post-operative ileus, a debilitating impairment of the gastrointestinal tract that occurs after surgery. A copy of the press release is attached hereto as Exhibit 99.1 and the information contained therein is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

The information furnished pursuant to Item 7.01 in this Form 8-K shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, unless we specifically incorporate it by reference in a document filed under the Securities Act of 1933 or the Securities Exchange Act of 1934. We undertake no duty or obligation to publicly update or revise the information furnished pursuant to Item 7.01 in this Form 8-K.

**Item 9.01 Financial Statements and Exhibits.**

(c) Exhibits

**Exhibit No.      Description**

99.1              Press Release dated October 25, 2006

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## 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 25, 2006



# Progenics

Pharmaceuticals, Inc.

**For Immediate Release**

**Contact:** Progenics Pharmaceuticals, Inc.  
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## **PROGENICS EARNS \$5 MILLION FROM WYETH FOR ACHIEVING METHYLNALTREXONE MILESTONE**

**Tarrytown, NY - October 25, 2006** - Progenics Pharmaceuticals, Inc. (NASDAQ: PGNX) today announced that it has earned a \$5 million payment from Wyeth Pharmaceuticals, a division of Wyeth (NYSE: WYE). This first milestone payment under the companies' collaborative agreement was triggered by Progenics' start of a phase 3 clinical trial of intravenous methylnaltrexone for the treatment of post-operative ileus (POI), a debilitating impairment of the gastrointestinal tract that occurs after surgery. Methylnaltrexone is an investigational drug that is designed to treat the peripheral side effects of opioid analgesics without interfering with pain relief. In December 2005, Wyeth and Progenics Pharmaceuticals entered into a collaboration to develop and commercialize methylnaltrexone. Under the terms of the agreement, Progenics has the potential to receive as much as \$356.5 million, including the payment announced today, payable upon achievement of certain milestones .

The previously announced phase 3 clinical study of intravenous methylnaltrexone in POI is enrolling approximately 500 patients who have undergone segmental colectomy surgery in a double-blind, randomized, placebo-controlled clinical trial at approximately 90 surgical centers worldwide. Key elements of the study design, including the primary efficacy endpoint, were reviewed with the United States Food and Drug Administration (FDA) under a Special Protocol Assessment in July 2006. In this trial, study medication (methylnaltrexone, at one of two dose levels, or placebo) is administered following surgery and every six hours until the patient recovers gastrointestinal function or for up to 10 days after surgery.

The intravenous form of methylnaltrexone currently under investigation for the treatment of post-operative ileus has received Fast Track designation from the FDA. Fast Track designation facilitates development and may expedite regulatory review of drugs that FDA recognizes as potentially addressing an unmet medical need for serious or life-threatening conditions. Progenics and Wyeth plan a second global phase 3 study, in a similar surgical setting, scheduled to begin later this year. Subsequent to satisfactory completion of these studies, a New Drug Application is planned for intravenous methylnaltrexone in late 2007 or early 2008.

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In a phase 2 study of intravenous methylnaltrexone in patients who had undergone segmental colectomy surgery, those individuals who received methylnaltrexone exhibited an acceleration of gastrointestinal recovery by at least one day on average compared to placebo. Significant improvements were seen in clinically important measures of gastrointestinal recovery: time to first bowel movement and discharge eligibility from the hospital. Methylnaltrexone was generally well tolerated in this study, with no reports of serious adverse events related to the drug. There are no medicines currently approved to treat POI. Post-operative ileus is a major contributor to prolonged hospital stays and therefore represents an important cause of increased health care costs. Because many postoperative patients cannot tolerate oral intake, including medications, intravenous methylnaltrexone may represent an important therapy for these patients.

## **Company Profile**

**Progenics Pharmaceuticals, Inc.**, of Tarrytown, NY is a biopharmaceutical company focusing on the development and commercialization of innovative therapeutic products to treat the unmet medical needs of patients with debilitating conditions and life-threatening diseases. Principal programs are directed toward symptom management and supportive care and the treatment of HIV infection and cancer. The Company has four product candidates in clinical development and several others in preclinical development. The Company, in collaboration with Wyeth, is developing methylnaltrexone for the treatment of opioid-induced side effects, including constipation and post-operative ileus. In the area of HIV infection, the Company is developing the viral-entry inhibitor PRO 140, a humanized monoclonal antibody targeting the HIV coreceptor CCR5 (in phase 1b studies). In addition, the Company is conducting research on ProVax, a novel prophylactic HIV vaccine. The Company is developing *in vivo* immuno-therapies for prostate cancer, including a human monoclonal antibody directed against prostate-specific membrane antigen (PSMA), a protein found on the surface of prostate cancer cells. Progenics is also developing vaccines designed to stimulate an immune response to PSMA. A recombinant PSMA vaccine is in phase 1 clinical testing. The Company is also developing a cancer vaccine, GMK, in phase 3 clinical trials for the treatment of malignant melanoma.

**PROGENICS DISCLOSURE NOTICE:** *The information contained in this document is current as of October 25, 2006. This press release contains forward-looking statements. Any statements contained herein that are not statements of historical fact may be forward-looking statements. When the Company uses the words 'anticipates,' 'plans,' 'expects' and similar expressions, it is identifying forward-looking statements. Such forward-looking statements involve risks and uncertainties which may cause the Company's actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. Such factors include, among others, the uncertainties associated with product development, the risk that clinical trials will not commence or proceed as planned, the risks and uncertainties associated with dependence upon the actions of our corporate, academic and other collaborators and of government regulatory agencies, the risk that our licenses to intellectual property may be terminated because of our failure to have satisfied performance milestones, the risk that products that appear promising in early clinical trials do not demonstrate efficacy in larger-scale clinical trials, the risk that we may not be able to manufacture commercial quantities of our products, the uncertainty of future profitability and other factors set forth more fully in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2005 and other reports filed with the Securities and Exchange Commission, to which investors are referred for further information. In particular, the Company cannot assure you that any of its programs will result in a commercial product.*

*Progenics does not have a policy of updating or revising forward-looking statements and assumes no obligation to update any forward-looking statements contained in this document as a result of new information or future events or developments. Thus, it should not be assumed that the Company's silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.*