

# PEREGRINE PHARMACEUTICALS INC

## FORM 8-K

(Current report filing)

Filed 05/28/10 for the Period Ending 05/28/10

Address	14282 FRANKLIN AVE TUSTIN, CA 92780
Telephone	7145086000
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Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	04/30

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

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**FORM 8-K**

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**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 28, 2010**

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**PEREGRINE PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State of other jurisdiction  
of incorporation)

**0-17085**  
(Commission File Number)

**95-3698422**  
(IRS Company  
Identification No.)

**14282 Franklin Avenue, Tustin, California 92780**  
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: **(714) 508-6000**

**Not Applicable**  
(Former name or former address, if changed since last report)

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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 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.**

On May 28, 2010, Peregrine Pharmaceuticals, Inc. issued a press release announcing new clinical trial data results from a Phase II trial evaluating bavituximab in combination with docetaxel in refractory patients with advanced breast cancer.

A copy of the press release is attached to this current report on Form 8-K as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits. The following material is filed as an exhibit to this Current Report on Form 8-K:

<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
99.1	Press Release issued May 28, 2010

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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.

PEREGRINE PHARMACEUTICALS, INC.

Date: May 28, 2010

By: /s/ Paul J. Lytle

Paul J. Lytle  
Chief Financial Officer and Corporate Secretary

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## EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued May 28, 2010

# PEREGRINE

Pharmaceuticals, Inc.

*Contact:*

Amy Figueroa  
Peregrine Pharmaceuticals  
info@peregrineinc.com  
(800) 987-8256

**NEW PROGRESSION-FREE SURVIVAL DATA FROM PEREGRINE'S BAVITUXIMAB IN  
PHASE II REFRACTORY BREAST CANCER TRIAL TO BE PRESENTED AT ASCO**

***-- 7.4 Months Median PFS for Refractory Breast Cancer Patients Treated with Bavituximab and Docetaxel --  
-- Planned Registrational Phase Iib Refractory Lung Cancer Trial to use Bavituximab and Docetaxel Combination --***

**TUSTIN, Calif., May 28, 2010** -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM), a clinical-stage biopharmaceutical company developing innovative monoclonal antibodies for the treatment of cancer and viral infections, today announced new median progression-free survival (PFS) data of 7.4 months from a Phase II trial evaluating bavituximab in combination with docetaxel in refractory patients with advanced breast cancer. Best overall response rate from this trial was 61% (28 of 46 patients) with 11% (5 of 46) of the patients achieving a clinical complete response. These results compare favorably to data from a separate published study showing an objective response rate of 41% with no complete responses in a similar patient population receiving docetaxel alone. These Phase II data will be highlighted in a poster presentation on June 5, 2010 at the ASCO Annual Meeting.

“With promising breast cancer data in both front-line and refractory patients, as well as in different therapeutic combinations and indications, Peregrine’s novel monoclonal antibodies offer broad-spectrum potential for the treatment of breast cancer and other solid tumors,” commented Alison Stopeck, M.D., Associate Professor of Medicine, director of clinical breast cancer program at the Arizona Cancer Center. “New cancer therapies that reactivate and direct the patient’s immune system are generating growing interest among cancer researchers and clinicians. Peregrine’s antibodies are a unique approach to treating cancer, targeting the highly specific immunosuppressive molecule called phosphatidylserine to reactivate the immune system response.”

Peregrine is planning to initiate a new registrational Phase Iib trial to evaluate bavituximab in combination with docetaxel in refractory non-small cell lung cancer (NSCLC) patients by mid-year. Bavituximab is a first-in-class phosphatidylserine (PS)-targeting monoclonal antibody that represents a new approach to treating cancer. PS is a highly immunosuppressive molecule usually located inside the membrane of healthy cells, but “flips” and becomes exposed on the outside of cells that line tumor blood vessels, creating a specific target for anti-cancer treatments. PS-targeting antibodies target and bind to PS and block this immunosuppressive signal, thereby enabling the immune system to recognize and fight the tumor.

“Bavituximab and docetaxel will be the combination therapy evaluated in our flagship trial, a registrational Phase Iib trial in refractory NSCLC patients expected to begin shortly, ” said Steven W. King, president and CEO of Peregrine. “The growing body of clinical and preclinical research provides further evidence of the broad-spectrum potential of our monoclonal antibodies as we prepare to initiate our two new Phase Iib trials in NSCLC as we pursue our goal of developing novel therapeutic options for cancer. We expect our investigator-sponsored trials program to add a new dimension to our data set as researchers explore new therapeutic combinations and potential indications for bavituximab.”

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### **About the Phase II Trial**

In Peregrine's refractory advanced breast cancer Phase II trial assessing bavituximab in combination with docetaxel, objective tumor response was 61% (28 of 46 patients), with 11% (5 of 46) of the patients achieving a clinical complete response. Median PFS in the trial was 7.4 months and median overall survival will be reported once these data mature. These results compare favorably to data from a separate published study showing an objective response rate of 41% with no complete responses in a similar patient population receiving docetaxel alone.

Peregrine's multi-center, open-label Phase II breast cancer trial was primarily intended to assess overall response rates to bavituximab combined with a refractory patient standard of care chemotherapeutic agent docetaxel. Secondary objectives of the study included measuring progression free survival, duration of response, overall patient survival and safety parameters. Patients were evaluated regularly for tumor response according to RECIST criteria.

### **About Breast Cancer**

The World Health Organization reports that breast cancer is the most commonly diagnosed cancer in women and is second only to lung cancer as a leading cause of female cancer deaths. The National Cancer Institute estimates that approximately 192,370 U.S. women will be diagnosed with breast cancer in 2009 and 40,170 women will die of the disease in the U.S. alone.

### **Poster at ASCO - Saturday, June 5, 2010, 2:00 – 6:00 pm CT**

*Phase II study of bavituximab plus docetaxel in locally advanced or metastatic breast cancer* (Abstract #1042) , Author: David Tabagari, Poster Board 22C, S Hall A2

Peregrine will also have a booth (#19114) for the duration of the 2010 ASCO Annual Meeting.

For more information on the ASCO conference, visit <http://chicago2010.asco.org/Home.aspx>.

### **About Peregrine Pharmaceuticals**

Peregrine Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company with a portfolio of innovative monoclonal antibodies in development for the treatment of cancer and serious viral infections. The company is pursuing three separate clinical programs in cancer and HCV infection with its lead product candidates bavituximab and Cotara<sup>®</sup>. Peregrine also has in-house manufacturing capabilities through its wholly owned subsidiary Avid Bioservices, Inc. ([www.avidbio.com](http://www.avidbio.com)), which provides development and biomanufacturing services for both Peregrine and outside customers. Additional information about Peregrine can be found at [www.peregrineinc.com](http://www.peregrineinc.com).

*Safe Harbor Statement: Statements in this press release which are not purely historical, including statements regarding Peregrine Pharmaceuticals' intentions, hopes, beliefs, expectations, representations, projections, plans or predictions of the future are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The forward-looking statements involve risks and uncertainties including, but not limited to, the risk that results from larger clinical trials will not be consistent with results experienced in earlier clinical trials and preclinical studies, the risk that the company may experience delays in patient enrollment for the planned phase IIb clinical trials, and risk that results may not support registration filings with the U.S. Food and Drug Administration. Factors that could cause actual results to differ materially or otherwise adversely impact the company's ability to obtain regulatory approval for its product candidates include, but are not limited to, uncertainties associated with completing preclinical and clinical trials for our technologies; the early stage of product development; the significant costs to develop our products as all of our products are currently in development, preclinical studies or clinical trials; obtaining additional financing to support our operations and the development of our products; obtaining regulatory approval for our technologies; anticipated timing of regulatory filings and the potential success in gaining regulatory approval and complying with governmental regulations applicable to our business. Our business could be affected by a number of other factors, including the risk factors listed from time to time in the company's SEC reports including, but not limited to, the annual report on Form 10-K for the year ended April 30, 2009 and the quarterly report on Form 10-Q for the quarter ended January 31, 2010. The company cautions investors not to place undue reliance on the forward-looking statements contained in this press release. Peregrine Pharmaceuticals, Inc. disclaims any obligation, and does not undertake to update or revise any forward-looking statements in this press release.*

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