

PEREGRINE PHARMACEUTICALS INC

FORM 8-K (Current report filing)

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Address	14282 FRANKLIN AVE TUSTIN, CA 92780
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 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): **March 9, 2012**

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 Employer 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)

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 March 9, 2012, Peregrine Pharmaceuticals, Inc. issued a press release announcing clinical data results from a randomized Phase II trial evaluating bavituximab in combination with carboplatin and paclitaxel in front-line non-small cell lung cancer patients.

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:

Exhibit
Number

99.1 Press Release issued March 9, 2012.

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: March 9, 2012

By: /s/ Paul J. Lytle

Paul J. Lytle
Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
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99.1	Press Release issued March 9, 2012.
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Contact:

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PEREGRINE REPORTS DATA FROM PHASE II FRONT-LINE LUNG CANCER TRIAL

-- Promising Progression-Free Survival From Site Assessments --

-- Overall Survival Endpoint from this Study Anticipated in Second Half of 2012 --

TUSTIN, CA –March 9, 2012- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM) today announced top-line overall response rate (ORR) and current median progression free survival (PFS) estimates from its phase II trial comparing bavituximab plus carboplatin and paclitaxel versus carboplatin and paclitaxel alone in patients with front-line Stage IIIb and Stage IV non-small cell lung cancer (NSCLC).

Based on investigator assessments, patients treated with bavituximab plus carboplatin and paclitaxel demonstrated a current median PFS estimate of 5.8 months versus 4.6 months in patients treated with carboplatin and paclitaxel alone, a 26% improvement. These results are consistent with a prior phase II single-arm study testing the same bavituximab combination in front-line NSCLC patients which showed a 6.1 month median PFS and with several prior published studies with carboplatin and paclitaxel in front-line patients that showed approximately a 4.5 month median PFS. Based on independent central imaging reads, patients demonstrated a current median PFS estimate of 6.7 months for the bavituximab-containing arm and 6.4 months for the chemotherapy-only arm. Peregrine expects to report median overall survival (OS) from this trial in the second half of 2012.

“We are pleased that the PFS results for the bavituximab-containing arm by both local and central image interpretation actually met or exceeded our expectations going into the study. While the data from the investigator assessments were in alignment with previous published reports for carboplatin and paclitaxel and suggested an encouraging difference between the treatment arms, the unexpected long PFS estimate for the control arm based on central reads confounds our ability to fully interpret this secondary efficacy endpoint,” said Joseph Shan, vice president, clinical & regulatory affairs at Peregrine. “We now await median OS data from this study which is the most clinically relevant endpoint from a drug development standpoint.”

Further data from the study showed that based on an independent central imaging review of eligible patients, patients treated with bavituximab plus carboplatin and paclitaxel demonstrated an ORR of 25%, versus 23% in patients treated with carboplatin and paclitaxel alone. Investigator-determined response rates were 32% for bavituximab plus carboplatin and paclitaxel versus 31% for carboplatin and paclitaxel alone.

“We continue to be enthusiastic about the bavituximab program and look forward to the upcoming data from seven ongoing clinical studies in multiple solid tumor indications including the OS data from this study. While we had hoped the PFS results in this study would be more consistent, we are encouraged by what we have seen so far in the trial and now look forward to the final and perhaps most important endpoint from the study, median OS,” said Steven W. King, president and chief executive officer of Peregrine. “We expect the remainder of the year to be an exciting one for the bavituximab program as data emerges from multiple solid tumor trials. In the coming months, we plan to unblind the second-line NSCLC Phase II trial and announce interim data from our Phase II trial in pancreatic cancer. In addition, we will be presenting bavituximab data at the upcoming annual AACR meeting on three of the four investigator-sponsored trials in various cancers.”

Bavituximab is currently being tested in seven clinical studies including three randomized Phase II trials in front-line and second-line non-small cell lung cancer (NSCLC), front-line pancreatic cancer and four investigator-sponsored trials (ISTs) in additional oncology indications with clinical data from each study expected in 2012.



About Peregrine's Randomized Phase II Front-Line NSCLC Trial

This randomized trial is designed to compare the ORR of carboplatin and paclitaxel with or without bavituximab in 86 patients with front-line, Stage IIIb/IV NSCLC. This analysis was performed on 83 protocol eligible patients (per protocol population) and ORR was determined by both investigators and independent central imaging review using RECIST (Response Evaluation Criteria in Solid Tumors). Secondary objectives of the study include median PFS, duration of response, median OS, and safety parameters. More information about this trial can be found at <http://www.clinicaltrials.gov/ct2/show/NCT01160601?term=bavituximab&rank=4>.

About Bavituximab

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.

About Peregrine Pharmaceuticals

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company with a portfolio of innovative monoclonal antibodies in clinical trials for the treatment of cancer and serious viral infections. The company is pursuing multiple clinical programs in cancer and infectious diseases with its lead product candidate bavituximab and novel brain cancer agent Cotara®. Peregrine also has in-house cGMP manufacturing capabilities through its wholly-owned subsidiary Avid Bioservices, Inc. (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.

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 the overall survival data together with the above reported data may not support registration filings with the U.S. Food and Drug Administration ("FDA"), the risk that results from the other randomized Phase II trial will not be consistent with results experienced in the earlier single-arm Phase II trial or support registration filings with the FDA, and the risk that Peregrine may not have or raise adequate financial resources to complete the planned clinical programs. 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, 2011 and the quarterly report on Form 10-Q for the quarter ended October 31, 2011. 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.
