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): February 19, 2013

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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).

o Soliciting material pursuant to Rule 14A-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR.14d-2(b))

o 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 February 19, 2013, Peregrine Pharmaceuticals, Inc. issued a press release providing updated data from its randomized, double-blind placebocontrolled Phase II trial of bavituximab in patients with second-line non-small cell lung 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:

Exhibit <u>Number</u>

99.1 Press Release issued February 19, 2013.

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: February 19, 2013

By: <u>/s/ Paul J. Lytle</u> Paul J. Lytle Chief Financial Officer

3

EXHIBIT INDEX

Exhibit <u>Number</u>

99.1

Description

Press Release issued February 19, 2013

4



Contact: Christopher Keenan or Jay Carlson Peregrine Pharmaceuticals, Inc. (800) 987-8256 <u>info@peregrineinc.com</u>

PEREGRINE PHARMACEUTICALS UPDATES TOP-LINE DATA FROM PHASE II CLINICAL TRIAL OF BAVITUXIMAB IN SECOND-LINE NON-SMALL CELL LUNG CANCER

-- 60% Improvement in Median Overall Survival in Patients Treated with Bavituximab Plus Docetaxel --

-- Data Support Advancing Bavituximab Into Phase III Development --

Tustin, CA - February 19, 2013 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM), today reported data from its randomized, double-blind placebocontrolled Phase II trial of bavituximab in patients with second-line non-small cell lung cancer (NSCLC). Data from the trial has been updated based on completion of an earlier review of discrepancies in the trial and the most current survival data from the trial. Updated results from this Phase II trial indicate a meaningful improvement in median overall survival of 11.7 months in the 3mg/kg bavituximab + docetaxel arm compared to 7.3 months in the control arm (HR=0.73; p value=0.217). Persistent separation in the survival curves was observed with response rates and progression free survival also favoring the 3mg/kg bavituximab + docetaxel arm in this difficult to treat second-line NSCLC. The results also demonstrated that bavituximab was well-tolerated with no significant differences in adverse events between the trial arms. Peregrine plans to report additional data from the trial, including updated subgroup analysis and safety data, at an upcoming scientific meeting.

"These compelling results strongly support advancing the 3mg/kg bavituximab plus docetaxel combination into Phase III development in second-line NSCLC," said Joseph Shan, vice president of clinical and regulatory affairs at Peregrine. "Data from this trial, along with results from seven other ongoing bavituximab trials across many different oncology indications, are helping guide our development efforts for this promising drug candidate. We look forward to reporting further data from these trials and to laying out our plans for advancing the program into late-stage development."

Peregrine's randomized, double-blind, placebo-controlled Phase II trial was designed to evaluate docetaxel with bavituximab or placebo and enrolled 121 patients with previously treated locally advanced or metastatic NSCLC. Patients enrolled in the trial were not selected based on genetic or other biomarkers. All patients had confirmed Stage IIIb or IV non-squamous NSCLC and had progressed following one prior chemotherapy regimen. The trial was designed to evaluate overall response rate (ORR) measured in accordance with RECIST criteria, progression-free survival (PFS), duration of response, overall survival (OS), and safety.

"From a regulatory standpoint, this trial achieved its three main goals in preparing for a Phase III trial by identifying a dose, augmenting the existing set of favorable bavituximab safety data, and demonstrating good signs of survival effect in patients," said Robert L. Garnick, Ph.D., head of regulatory affairs at Peregrine. "With these data in hand, we are now preparing for additional discussions with regulatory bodies including an end-of-Phase II meeting with the FDA by mid-year with an overall goal of being in a position to initiate a pivotal trial near year-end."

"The conservative approach we took following our internal review of data from this trial combines one of our bavituximab treatment arms with the placebo group with the resulting data remaining compelling to advance the program into Phase III development in second line NSCLC. We remain confident that the trial has demonstrated the potential of bavituximab in this difficult to treat disease," said Steven W. King, president and chief executive officer of Peregrine. "While our clinical, regulatory and manufacturing teams work together to prepare for an end-of-Phase II meeting with the FDA, we are continuing to update potential partners on these trial results and our future plans for advancing the program. Partnering interest remains high and the updates from this trial should help advance these discussions. We would like to express our gratitude to the patients who participated in the trial and look forward to continuing to develop potential treatments for cancer."

Background on Vial Coding Discrepancy

The review was prompted by the discovery of vial coding discrepancies while preparing for an end-of-Phase II meeting with the FDA as announced on September 24, 2012. The internal review included a thorough operational review of multiple third-party vendor operations at sites worldwide, testing of investigational product used in the trial, additional patient sample testing to determine drug levels and a review of immunogenicity testing results from the trial. The initial results of the extensive internal review were announced on January 7, 2013 and indicated that discrepancies were isolated to the placebo and 1mg/kg treatment arms of the trial and that there was no evidence of discrepancies in the 3mg/kg treatment arm of the trial. Based on the results of the internal review, Peregrine has taken a conservative approach toward analyzing the results from the trial which included combining the placebo and 1mg/kg arms into one treatment arm (control arm), and comparing those results to the 3mg/kg arm.

About Bavituximab

Bavituximab is a first-in-class phosphatidylserine (PS)-targeting monoclonal antibody that represents a new approach to treating cancer. Bavituximab is the lead drug candidate from the company's PS technology platform and is currently being tested in eight clinical trials, including three randomized Phase II trials in front-line and second-line non-small cell lung cancer and front-line pancreatic cancer, and five investigator-sponsored trials (ISTs) in additional oncology indications. 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, Inc.

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company with a portfolio of innovative monoclonal antibodies in clinical trials focused on the treatment and diagnosis of cancer. The company is pursuing multiple clinical programs in cancer 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. (<u>www.avidbio.com</u>), which provides development and biomanufacturing services for both Peregrine and outside customers. Additional information about Peregrine can be found at <u>www.peregrineinc.com</u>.

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 major discrepancies discovered with respect to our randomized, double-blind placebo-controlled Phase II trial of bavituximab in patients with refractory NSCLC may cause regulatory authorities to require further clinical trials to support a registration package, the risks that partnering discussions may not result in a partnering transaction or that such discussions could be hindered or delayed as a result of the potential impact on the regulatory pathway for bavituximab caused by the major discrepancies discovered with respect to the Phase II NSCLC trial or the existing class action lawsuits, the risk that results from the front-line NSCLC trail will not be consistent with results experienced in earlier trials and may not support advancing this indication into later stage trials. It is important to note that the Company's actual results could differ materially from those in any such forward-looking statements. Factors that could cause actual results to differ materially 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 our SEC reports including, but not limited to, the annual report on Form 10-K for the fiscal year ended April 30, 2012 and quarterly report on Form 10-Q for the quarter ended October 31, 2012. 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.