

**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): **January 6, 2014**

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 January 6, 2014, Peregrine Pharmaceuticals, Inc. issued a press release announcing that it had received Fast Track designation by the U.S. Food and Drug Administration for its lead investigational immunotherapy bavituximab for the potential treatment of 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
Number**

99.1 Press Release issued January 6, 2014.

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: January 6, 2014

By: /s/ Paul J. Lytle

Paul J. Lytle
Chief Financial Officer

EXHIBIT INDEX

**Exhibit
Number**

Description

99.1 Press Release issued January 6, 2014



Contact:

Christopher Keenan or Jay Carlson
Peregrine Pharmaceuticals, Inc.
(800) 987-8256
info@peregrineinc.com

**PEREGRINE PHARMACEUTICALS RECEIVES FDA FAST TRACK DESIGNATION FOR ITS IMMUNOTHERAPY
BAVITUXIMAB AS A POTENTIAL TREATMENT OF SECOND-LINE NON-SMALL CELL LUNG CANCER**

-- SUNRISE Pivotal Phase III Trial of BavItuximab in Second-Line NSCLC Underway --

TUSTIN, CA - January 6, 2014 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM), today announced that the company has received Fast Track designation by the U.S. Food and Drug Administration (FDA) for its lead investigational immunotherapy bavituximab for the potential treatment of second-line non-small cell lung cancer (NSCLC). Recently, the company initiated SUNRISE, a pivotal Phase III clinical trial comparing bavituximab plus the chemotherapy docetaxel against placebo plus docetaxel in this indication.

“The fast track designation is a milestone for the SUNRISE trial program and represents a step closer to bringing bavituximab to the market,” said Robert Garnick, Ph.D., head of regulatory affairs at Peregrine. “We are very pleased that the FDA has recognized the potential of this novel therapy as a treatment for this serious and devastating type of cancer and look forward to working closely with them to ensure the most efficient review process.”

The Fast Track programs of the FDA are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Fast track status enables a sponsor to have more frequent and timely communication and meetings with the FDA regarding product development plans and may also result in eligibility for priority review of New Drug Applications. Fast track designation does not apply to a product alone but a combination of a product and specific indication.

SUNRISE (“Stimulating ImmUne RespoNse thRough BavItuximab in a PhaSE III Lung Cancer Study”) is a Phase III, global, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety, tolerability and efficacy of bavituximab plus docetaxel in patients with second-line non-small cell lung cancer (NSCLC). The trial is evaluating bavituximab plus docetaxel versus docetaxel plus placebo in approximately 600 patients at more than 100 clinical sites worldwide. Patients with Stage IIb/IV non-squamous, NSCLC who have progressed after standard front-line treatment are eligible for enrollment. Patients will be randomized into 1 of 2 treatment arms. All patients will receive up to six 21-day cycles of docetaxel (75 mg/m²) plus weekly infusions of either bavituximab (3mg/kg) or placebo until progression or toxicity. The primary endpoint of the trial will be overall survival. For additional information about the SUNRISE trial please visit www.sunrisetrial.com or ClinicalTrials.gov using Identifier NCT01999673.

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. These data detailing the immune-stimulatory mechanism of action of PS-targeting antibodies, such as the company's lead drug candidate bavituximab, are the subject of a manuscript published in the October 2013 issue of the American Association for Cancer Research (AACR) peer-reviewed journal, *Cancer Immunology Research*. Bavituximab is currently being evaluated in several solid tumor indications, including non-small cell lung cancer, breast cancer, liver cancer and rectal cancer with a trial in advanced melanoma anticipated to initiate in the near future.

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 immunotherapy candidate bavituximab while seeking a partner to further advance its 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 third-party 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 enrollment of the Phase III trial may experience delays or take longer than anticipated, the risk that the results from the Phase III trial may not support a future Biologics License Application (BLA) submission, the risk that the company may not have or raise adequate financial resources to complete the Phase III trial and the risk that the company may not find a suitable partner for the Phase III trial or the PS program. 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 our reports filed with the Securities and Exchange Commission including, but not limited to, our annual report on Form 10-K for the fiscal year ended April 30, 2013 and quarterly report on Form 10-Q for the quarter ended October 31, 2013. 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.
