## 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): October 30, 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):

- 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 October 30, 2014, Peregrine Pharmaceuticals, Inc. issued a press release reporting data from the Phase Ib investigator-sponsored trial of its immunotherapy bavituximab in combination with the chemotherapies pemetrexed and carboplatin in patients with previously untreated, locally advanced or metastatic non-squamous 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 October 30, 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: October 30, 2014

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

#### EXHIBIT INDEX

Exhibit	
Number	Description

99.1 Press Release issued October 30, 2014.



Contact:
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## PROMISING DATA PRESENTED AT THE CHICAGO MULTIDISCIPLINARY SYMPOSIUM ON THORACIC ONCOLOGY FROM AN INVESTIGATOR-SPONSORED TRIAL OF PEREGRINE PHARMACEUTICALS' BAVITUXIMAB IN COMBINATION WITH PEMETREXED AND CARBOPLATIN IN FRONT-LINE NON-SMALL CELL LUNG CANCER

- Favorable Trends in Both Overall Response Rates of 35% and Median Overall Survival of 12.2 Months Continue to Support Bavituximab's Potential in NSCLC
  - Lead Immuno-Oncology Antibody Bavituximab in a Phase III Trial in Patients with Previously Treated Non-Small Cell Lung Cancer-

TUSTIN, CA October 30, 2014 - Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM) (NASDAQ: PPHMP), today announced the presentation of data from the Phase Ib investigator-sponsored trial (IST) of its immunotherapy bavituximab in combination with the chemotherapies pemetrexed and carboplatin in patients with previously untreated, locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC). Data from this single-arm, open-label, multi-center trial show an overall tumor response (ORR) of 35%, a median progression-free-survival (PFS) of 4.8 months, and a median overall survival (OS) of 12.2 months. Favorable trends in ORR and OS continue to support bavituximab's potential in NSCLC.<sup>1-4</sup> These data are presented in a poster session at the 2014 Chicago Multidisciplinary Symposium on Thoracic Oncology being held at the Marriott Downtown Chicago Magnificent Mile in Chicago, Illinois.

"While we continue to advance our SUNRISE Phase III trial in second-line NSCLC, data from this front-line trial are intriguing and warrant further investigation in a larger trial setting," said Joseph Shan, vice president of clinical and regulatory affairs of Peregrine. "These recent data add to the growing body of favorable combination data generated with bavituximab and chemotherapy agents as well as complementing the preclinical data emerging from our immuno-oncology program combining bavituximab with immune checkpoint inhibitors." <sup>5-8</sup>

The poster titled: "A Phase Ib Study of Bavituximab Plus Carboplatin and Pemetrexed in Chemotherapy Naïve Stage IV Non-Squamous Non-Small Cell Lung Cancer" will be presented by Juneko Grilley-Olson, M.D., principal investigator of the trial and assistant professor, Department of Medicine, Division of Hematology and Oncology at the University of North Carolina at Chapel Hill. Results from 23 evaluable patients with advanced non-squamous NSCLC showed that the combination of bavituximab, carboplatin and pemetrexed was well-tolerated and clinically active. In this single-arm trial, patients treated with bavituximab in combination with carboplatin and pemetrexed achieved an objective response rate (ORR) of 35% (95% confidence interval (CI): 16.4 - 57.3%) as measured in accordance with RECIST (Response Evaluation Criteria in Solid Tumors) criteria. In addition, data showed a current median PFS of 4.8 months (95% CI: 4.0 - 8.0 months) and a median OS of 12.2 months (95% CI: 8.0 − not estimable (NE) months). Most adverse events (AE) observed were consistent with the known safety profile of the chemotherapy agents with no dose-limiting toxicities (DLT) or unexpected AEs occurring. All patients experienced at least one AE. The most common treatment related AEs were thrombocytopenia, anemia, neutropenia, fatigue, nausea with most AEs being ≤ Grade 2. The recommended Phase II dose of bavituximab in combination with carboplatin and pemetrexed is determined to be 3mg/kg.

Dr. Grilley-Olson stated: "I am pleased to be presenting these updated results to the oncology community given the encouraging data coming from this open-label trial in what is a difficult to treat disease. While these data come from a small number of patients the responses seen warrant further clinical examination including the conduct of randomized trials. In addition, the survival curve observed from this trial is consistent with those seen from other immunotherapy-based drug candidates."

Bavituximab is in Phase III development for the treatment of previously treated non-small lung cancer as part of the SUNRISE trial and is being evaluated in several solid tumor indications, including investigator-sponsored trials in breast cancer, liver cancer, rectal cancer and melanoma.

#### **About the Phase Ib Trial**

This is a Phase Ib, open-label, single-arm, multi-center trial in 26 patients with previously untreated, locally advanced or metastatic non-squamous NSCLC. These patients received up to six 21-day cycles of the drugs pemetrexed and carboplatin with weekly bavituximab (3 mg/kg) until progression or toxicity. The primary endpoints of the trial were to determine the safety, dose-limiting toxicity (DLT) and recommended Phase II dose of bavituximab in combination with carboplatin and pemetrexed in advanced non-squamous NSCLC. Secondary endpoints included assessment of overall response rate (ORR) measured by RECIST criteria, progression-free survival (PFS) and overall survival (OS).

More information on this trial can be found at www.ClinicalTrials.gov using Identifier NCT01323062.

The link to the poster can be found from the front page of the company's website at: www.peregrineinc.com.

About Peregrine Pharmaceuticals, Inc.

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company with a pipeline of novel drug candidates in clinical trials for the treatment and diagnosis of cancer. The company's lead immunotherapy candidate, bavituximab, is in Phase III development for the treatment of previously treated non-small lung cancer (the "SUNRISE trial") along with several investigator-sponsored trials evaluating other treatment combinations and additional oncology indications. The company is also advancing a molecular imaging agent, 124I-PGN650, in an exploratory clinical trial for the imaging of multiple solid tumor types. 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 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 later stage clinical trials may not correlate to the results from earlier stage clinical 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 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, 2014 as well as any updates to these risk factors filed from time to time in the company's other filings with the Securities and Exchange Commission. The company cautions investors not to place undue reliance on the forward-looking statements in this press release. Peregrine Pharmaceuticals, Inc. disclaims any obligation, and does not undertake to update or revise any forward-lookin

- <sup>1</sup> Shtivelband M. et al. "Randomized, blinded, placebo-controlled phase II trial of docetaxel and bavituximab as second-line therapy in locally advanced or metastatic non-squamous non-small cell lung cancer." J Clin Oncol 31, 2013 (suppl; abstr 8095)
- <sup>2</sup> Chalasani P et al. Phase I clinical trial of bavituximab (Bavi) and paclitaxel (P) in patients (pts) with HER2-negative metastatic breast cancer (MBC). J Clin Oncol 31, 2013 (suppl; abstr 567)
- <sup>3</sup> Raghunadharao D. et al Bavituximab plus paclitaxel and carboplatin for the treatment of advanced non-small-cell lung cancer Lung Cancer. Published Online: August 23, 2014 DOI: http://dx.doi.org/10.1016/j.lungcan.2014.08.010
- <sup>4</sup> Peregrine Pharmaceuticals. Peregrine Reports Promising 20.7 Month Median Overall Survival From Phase II Advanced Breast Cancer Trial. N.p., 24 Aug. 2011. Web. 24 Aug. 2011
- <sup>5</sup> Brekken R. Antibody-mediated blockade of phosphatidylserine enhances the anti-tumor activity of immune checkpoint inhibitors by affecting myeloid-derived suppressor cell (MDSC) and lymphocyte populations in the tumor microenvironment. Presentation at Cancer Research Institutes' "Cancer Immunotherapy: Out of the Gate" conference October 6, 2014. New York, New York
- <sup>6</sup> Hutchins J. Phosphatidylserine (PS)-Targeting Antibodies Enhance Activity of Immune Checkpoint Inhibitors by Repolarizing Immunosuppressive Immune Cells Populating the Tumor Microenvironment. Presentation at Cambridge Healthcare Institute's ImVacS 9th Annual Immunotherapies & Vaccine Summit. August 11, 2014. Boston, Massachusetts
- <sup>7</sup> Huang X et al. Phosphatidylserine-targeting antibody synergizes with anti-PD-1 antibody to inhibit tumor growth in K1735 mouse melanoma model. In: Proceedings of the 105th Annual Meeting of the American Association for Cancer Research; 2014 Apr 5-9; San Diego, CA. Philadelphia (PA): AACR; Cancer Res 2014;74(19 Suppl): Abstract nr LB-262. doi:10.1158/1538-7445.AM2014-LB-262
- <sup>8</sup> Gong J. et al, Targeting of phosphatidylserine by monoclonal antibodies enhances activity of immune checkpoint inhibitors in tumors. In: Proceedings of the 105th Annual Meeting of the American Association for Cancer Research; 2014 Apr 5-9; San Diego, CA. Philadelphia (PA): AACR; Cancer Res 2014;74(19 Suppl): Abstract nr 4978. doi:10.1158/1538-7445.AM2014-4978