

# PEREGRINE PHARMACEUTICALS INC

## **FORM 8-K** (Current report filing)

Filed 10/11/16 for the Period Ending 10/10/16

Address	14282 FRANKLIN AVE TUSTIN, CA 92780
Telephone	7145086000
CIK	0000704562
Symbol	PPHM
SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	04/30

**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 10, 2016**

---

**PEREGRINE PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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

**001-32839**  
(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:

- 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))
-

**Item 8.01 Other Events.**

On October 10, 2016, Peregrine Pharmaceuticals, Inc. issued a press release reporting top-line results and initial biomarker data from its Phase III SUNRISE trial of bavituximab in patients with previously treated locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC).

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 October 10, 2016.

**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 10, 2016

By: /s/ Paul J. Lytle  
Paul J. Lytle  
Chief Financial officer

**EXHIBIT INDEX**

<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
99.1	Press Release issued October 10, 2016.



Contacts:

Stephanie Diaz (Investors)  
 Vida Strategic Partners  
 415-675-7401  
 sdiaz@vidasp.com

Tim Brons (Media)  
 Vida Strategic Partners  
 415-675-7402  
 tbrons@vidasp.com

**Peregrine Pharmaceuticals Reports Top-Line and Initial Biomarker Data from Phase III SUNRISE Trial of Baviximab in Oral Presentation at European Society for Medical Oncology (ESMO) 2016 Congress**

*-- Company Has Identified Beta-2 Glycoprotein-1 ( $\beta$ 2GP1) as a Biomarker that Correlates with Statistically Significant Improvement in Overall Survival for Patients Receiving the Baviximab Combination Compared to Chemotherapy Alone --*

*-- Ongoing SUNRISE Trial Biomarker Analysis Expected to Identify Additional Biomarkers Associated with Patients Benefiting from Baviximab Treatment that Will Help Guide Program's Future Clinical Development --*

**TUSTIN, Calif., October 10, 2016** -- Peregrine Pharmaceuticals, Inc. (NASDAQ:PPHM) (NASDAQ:PPHMP), a biopharmaceutical company committed to improving patient lives by manufacturing high quality products for biotechnology and pharmaceutical companies and advancing its proprietary R&D pipeline, today reported that top-line data from the Phase III SUNRISE trial of baviximab in patients with previously treated locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) were presented in an oral presentation at the European Society for Medical Oncology (ESMO) 2016 Congress. The presentation included interim efficacy and safety outcomes, as well as initial findings from the company's ongoing biomarker analysis of samples collected during the study. The SUNRISE Phase III trial was discontinued earlier this year based on a pre-specified interim analysis although patient treatment and follow-up in the study were allowed to continue. The pre-planned biomarker analysis has been taking place as patient follow-up has continued and available results were evaluated as part of the recent top-line data analysis.

The study protocol pre-specified the collection of thousands of patient samples for exploratory analyses over a wide range of possible biomarkers, including pre-treatment levels of beta-2 glycoprotein-1 ( $\beta$ 2GP1). Data presented at ESMO demonstrated that patients with pre-treatment  $\beta$ 2GP1 levels between 200 and 240 (representing approximately 30% of randomized patients) achieved a statistically significant, 5.5-month improvement (13.2 months vs. 7.7 months) in median overall survival (OS) as compared to patients in the control group with the same range of  $\beta$ 2GP1 levels [ $p = 0.049$ ; hazard ratio (HR) = 0.67]. A similar trend was observed with pre-treatment  $\beta$ 2GP1 levels  $\geq 200$   $\mu$ g/mL (representing approximately 50% of randomized patients) with 11.9 months vs. 10.1 months median OS in favor of the baviximab-containing group ( $p = 0.155$ ; HR = 0.81). Taken together, this strongly suggests  $\beta$ 2GP1 levels may be useful for identifying patients who are more likely to benefit from a baviximab containing therapeutic regimen. Numerous additional biomarkers are currently being analyzed with the goal of developing a multi-marker signature that can potentially identify patients that are likely to receive significant clinical benefit from a baviximab-containing therapeutic regimen.

Top-line results reported at ESMO today were based on a data cut-off after 70% (330/473) of the targeted OS events had been reached and demonstrated the addition of baviximab to docetaxel did not result in improvement of the study's primary endpoint of OS in the intent-to-treat population. Median OS for the baviximab plus docetaxel group was 10.7 months as compared to 10.8 months for the placebo plus docetaxel control group (HR = 1.110;  $p = 0.382$ ). Median progression free survival (PFS) for the baviximab-containing group was 4.1 months compared to 3.9 months for the control group (HR = 0.97;  $p = 0.803$ ). Objective response rates based on independent central review are currently 13% and 11% ( $p = 0.53$ ) for the baviximab-containing and control groups, respectively. Additionally, the safety profile of the combination of baviximab with docetaxel was similar to placebo plus docetaxel.

"With every clinical trial we conduct, we are constantly reminded of the difficulty involved in treating patients with non-small cell lung cancer. This continues to prove to be a very challenging cancer to combat and the need for effective treatments remains high," David R. Spigel, MD, chief scientific officer and program director of Lung Cancer Research at the Sarah Cannon Research Institute and one of the lead investigators in the SUNRISE trial. "The findings with regard to  $\beta$ 2GP1 that have been collected as part of the ongoing SUNRISE trial data analysis are interesting and support further investigation."

Peregrine intends to further evaluate the role of  $\beta$ 2GPI levels in response to bavituximab therapy in future clinical trials. The company has filed a new patent application directed to the use of this initial biomarker discovery. Additional patient sample testing and analysis is ongoing and may result in other biomarkers of importance.

“We would once again like to thank all of the patients, clinical investigators and scientists who participated in the SUNRISE trial and have made it possible for us to continue to collect and analyze a range of key data from the study. While we were disappointed with the trial being discontinued earlier in the year, we are excited by the fact that we are beginning to learn important information from the trial through the ongoing biomarker analysis program that will be critical in helping guide the future clinical development of bavituximab,” said Joseph Shan, vice president of clinical and regulatory affairs at Peregrine. “It is encouraging that the initial biomarker analysis has identified an important biomarker early in the process and we are optimistic that additional biomarkers associated with improved outcomes for bavituximab-containing treatments will be identified as the analysis continues. We expect to be able to share the emerging data over the coming months at scientific and medical conferences as the more results become available.”

Mr. Shan continued, “It is not uncommon in the cancer field for therapeutic candidates to suffer clinical trial setbacks as researchers continue to learn more about the most appropriate patient populations for those drugs. In this landscape, biomarkers play an increasingly important role in helping identify specific patient characteristics that may impact responses to a treatment. This has been seen historically with targeted cancer treatments, as well as more recently with checkpoint inhibitors including PD-1 inhibitors. We look forward to identifying the equivalent markers for bavituximab that will help guide its clinical development.”

Bavituximab is an investigational chimeric monoclonal antibody that targets phosphatidylserine (PS). Signals from PS inhibit the ability of immune cells to recognize and fight tumors. Bavituximab is believed to override PS mediated immunosuppressive signaling by blocking the engagement of PS with its receptors as well as by sending an alternate immune activating signal. PS targeting antibodies have been shown to shift the functions of immune cells in tumors, resulting in multiple signs of immune activation and anti-tumor immune responses.

Peregrine’s clinical development strategy for bavituximab is currently focused on small, early-stage proof-of-concept trials evaluating the drug in combination with other cancer treatments. The intent behind this strategy is to control research and development costs, while continuing to generate clinical data to further validate bavituximab’s combination potential that will be critical to bringing onboard a partner to help advance the program.

#### **About Peregrine Pharmaceuticals, Inc.**

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company committed to improving the lives of patients by delivering high quality pharmaceutical products through its contract development and manufacturing organization (CDMO) services and through advancing and licensing its investigational immunotherapy and related products. Peregrine’s in-house CDMO services, including cGMP manufacturing and development capabilities, are provided 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 third-party customers. The company is also working to evaluate its lead immunotherapy candidate, bavituximab, in combination with immune stimulating therapies for the treatment of various cancers, and developing its proprietary exosome technology for the detection and monitoring of cancer. For more information, please visit [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 further evaluation of the role of  $\beta$ 2GPI levels in response to bavituximab therapy does not indicate statistically significant improvements in overall survival correlated with  $\beta$ 2GPI levels for patients, the risk that the company does not identify additional biomarkers identifying patients most likely to respond to bavituximab treatment, and the risk that the company is unable to secure patent protection directed to the use of  $\beta$ 2GPI levels as a biomarker. 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, 2016 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 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.*