

# PEREGRINE PHARMACEUTICALS INC

## FORM 8-K (Current report filing)

Filed 12/29/11 for the Period Ending 12/29/11

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

Washington, DC 20549

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **December 29, 2011**

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**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)

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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 December 29, 2011, Peregrine Pharmaceuticals, Inc. issued a press release announcing preliminary clinical data results from a randomized Phase II trial evaluating bavituximab in patients with Hepatitis C virus infection.

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 December 29, 2011.

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**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: December 29, 2011

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

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## EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Description</b>
99.1	Press Release issued December 29, 2011



Peregrine Contact:  
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Peregrine Pharmaceuticals  
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#### PEREGRINE PROVIDES UPDATE ON HCV CLINICAL PROGRAM

-- Preliminary Data from Phase II Study Shows Antiviral Activity and Positive Safety Profile at Both Bavituximab Doses Evaluated; Supporting Further Dosing and Combination Studies --

-- Company to Seek Collaboration to Advance HCV Program While Continuing to Focus on its Lead Bavituximab Clinical Program in Multiple Solid Tumor Indications Including Lung Cancer --

TUSTIN, CA, December 29, 2011 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM), a clinical-stage biopharmaceutical company developing first-in-class monoclonal antibodies for the treatment of cancer and viral infections, today provided an update from its randomized Phase II bavituximab study in patients infected with genotype-1 chronic hepatitis C virus (HCV). Patients were randomized in the three-arm study to receive one of two doses of bavituximab (0.3mg/kg or 3mg/kg) or pegylated interferon alpha-2a, in combination with ribavirin. The goals of the study were to determine if bavituximab plus ribavirin has a better safety profile as compared to interferon plus ribavirin, to confirm that the combination of bavituximab and ribavirin has antiviral activity defined as 12 week early virologic response (EVR) <sup>1</sup> and to compare antiviral activity of peg-interferon plus ribavirin versus bavituximab plus ribavirin.

A preliminary data analysis indicates that the combination of bavituximab and ribavirin appeared safe and well tolerated with patients reporting fewer side effects than in the interferon-containing arm. Initial data from the study also indicated that both dose levels of bavituximab with ribavirin demonstrated antiviral activity, however the antiviral effects in patients receiving the 0.3 mg/kg dosing level were more pronounced. A comparison of the viral data indicated that the kinetics of antiviral activity were different between the interferon and bavituximab treatment groups with a high percentage of those patients achieving EVR in the interferon arm of the study doing so between week 4 and 8 and the majority of patients achieving EVR in the bavituximab groups doing so at the week 12 end of study timepoint. More patients had achieved EVR in the interferon-containing group by the end of the study, however based on the nature of late EVR development in the bavituximab containing arms at the very end of the 12 week trial, a longer-term evaluation is needed to adequately compare the effectiveness of bavituximab and interferon. The company plans to present full results from the study at a medical conference in 2012.

“We are pleased with the initial results we have seen from this clinical study evaluating the combination of bavituximab with an established antiviral drug in HCV patients. We see good evidence that the combination of bavituximab with ribavirin has a better safety profile than an interferon containing regimen which was one of the primary objectives of the study,” said Joseph S. Shan, vice president of clinical and regulatory affairs at Peregrine Pharmaceuticals. “In addition, we also see that while both dose levels of bavituximab were active, the lower dose level appears more active in HCV patients than the high dose level. Taken together, these early results are very important in validating that the combination of bavituximab with its immunological mechanism of action with an active antiviral agent has a good safety profile and promising antiviral activity. These results suggest that future studies evaluating longer bavituximab treatment durations at or around the lower dose level in combination with ribavirin and potentially direct acting antivirals in certain patient populations may hold promise as interferon-free HCV therapeutic regimens.”

“The early data from this trial are promising and suggest that continued development of bavituximab in HCV patients is warranted to explore the full immune-modulating potential of the compound in combination with antiviral agents,” said Steven W. King, president and chief executive officer of Peregrine. “With this data in hand, we plan to actively seek development partners interested in working with us to move the PS-targeting antiviral program forward while we continue to focus our resources on the advancement of our bavituximab oncology clinical program in multiple solid tumor indications including non-small cell lung cancer (NSCLC) and pancreatic cancers as well as other indications with high unmet medical need. With as many as six data points coming over the next six months or so from our ongoing phase II trials in front and second line NSCLC and the additional possible data points coming from five additional oncology trials, this is a good time to seek partners for the antiviral program which has shown promise in this study. We look forward to sharing full data from the HCV trial in 2012 and to moving the program forward in the future.”

1. EVR is defined as equal or greater than a 2 log reduction in HCV RNA from baseline.

### **About the Phase II HCV Trial**

In this multicenter Phase II randomized trial, 66 patients with previously untreated genotype-1 chronic HCV infection were randomly assigned to one of three treatment arms. Patients received daily oral ribavirin (1000 mg) with either weekly bavituximab (0.3 mg/kg or 3 mg/kg) or pegylated interferon alpha-2a (180 µg) for up to 12 weeks and were tested for safety parameters and antiviral activity.

### **About Bavituximab's Antiviral Approach**

Bavituximab is the first in a new class of patented antibody therapeutics that target and bind to phosphatidylserine (PS), a specific phospholipid component of cell membranes. Bavituximab helps reactivate and direct the body's immune system to destroy infected cells and virus particles that exhibit this specific phospholipid on their surface. Since their target is host-derived rather than pathogen-derived, PS-targeting antibodies have the potential for broad-spectrum antiviral activity and are also expected to be much less susceptible to the viral mutations that often lead to drug resistance.

### **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 hepatitis C virus infection 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](http://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](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 results from the randomized Phase II trial will not be consistent with results experienced in the earlier single-arm Phase I studies, the risk that results from the randomized Phase II trial may not support registration filings with the U.S. Food and Drug Administration, the risk that Peregrine may not have or raise adequate financial resources to complete the planned clinical programs, and the risk that Peregrine will not find a development partner interested in the antiviral applications of its PS-targeting technology. 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 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.

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