# 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): November 22, 2011

### 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).
- 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))
- 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 November 22, 2011, Peregrine Pharmaceuticals, Inc. issued a press release announcing clinical data results from a Phase II trial evaluating bavituximab in combination with carboplatin and paclitaxel in patients with locally advanced or metastatic breast 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 November 22, 2011.

#### SIGNATURES

Pursuant to the requirements	of the	Securities	Exchange	Act o	f 1934,	the	Registrant	has dul	y caused	this	report	to be	e signed	on	its beha	lf by	the
undersigned hereunto duly authorized.																	

PEREGRINE PHARMACEUTICALS, INC.

By: <u>/s/ Paul J. Lytle</u> Paul J. Lytle Date: November 22, 2011

Chief Financial Officer

#### EXHIBIT INDEX

Exhibit

Number Description

99.1 Press Release issued November 22, 2011



Contact:
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Peregrine Pharmaceuticals
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info@peregrineinc.com

## PEREGRINE REPORTS PROMISING 23.2 MONTH MEDIAN OVERALL SURVIVAL FROM PHASE II ADVANCED BREAST CANCER TRIAL

-- Data Show Consistent Trend with Earlier 74% Tumor Response Rate and 6.9 Months Median PFS --

TUSTIN, CA, November 22, 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 announced 23.2 month median overall survival (OS) from a single-arm Phase II trial evaluating bavituximab in combination with carboplatin and paclitaxel in patients with locally advanced or metastatic breast cancer. In a separate published study using a similar chemotherapy regimen of carboplatin and paclitaxel median OS was 16.0 months in a similar patient population. Currently, Peregrine's bavituximab is being evaluated in randomized Phase II trials in non-small cell lung cancer (NSCLC), pancreatic cancer, and hepatitis C virus (HCV), as well as in four investigator-sponsored trials (ISTs) in additional oncology indications, including HER2-negative metastatic breast cancer.

"In all three of our prior signal-seeking trials, the survival data have been very promising, translating closely from earlier tumor response data, and we are excited to be developing bavituximab in combination with chemotherapy for a broad range of cancer patients," said Kerstin B. Menander, M.D. Ph.D., head of medical oncology at Peregrine Pharmaceuticals. "Standard chemotherapy upregulates bavituximab's phosphatidylserine (PS) target on tumor blood vessel cells, providing rationale for potential synergistic effects as well as in the treatment of refractory patients who have not responded to prior chemotherapy. We are eager to analyze and report data from our ongoing randomized Phase II trials and ISTs evaluating bavituximab's broad therapeutic potential."

In Peregrine's prior single-arm, multi-center Phase II trial, 46 patients with locally advanced or metastatic breast cancer who had previously been treated with surgery, radiation, chemotherapy, or hormone therapy were treated with weekly bavituximab in combination with carboplatin and paclitaxel. The primary endpoint objective response rate (ORR) was 74%, with 24% of the patients achieving a clinical complete response (CR) in accordance with RECIST criteria. In a separate historical control trial<sup>1</sup>, 76 evaluable patients treated with weekly carboplatin and paclitaxel alone, ORR was 62%, with 8% of patients achieving a CR. Secondary endpoint median progression-free survival (PFS) was 6.9 months for patients in Peregrine's trial. Time to progression (TTP) was 4.8 months in the historical control trial. Neither of these earlier studies selected patients based on hormone receptor status.

#### About the IST in HER2-Negative Metastatic Breast Cancer

In this Phase I single-arm, open-label trial, up to 14 patients with HER2-negative metastatic breast cancer are being treated with paclitaxel (80 mg/m²) weekly for three weeks out of each four-week cycle and bavituximab (3 mg/kg) weekly. Patients will be treated until disease progression or intolerable toxicity. The primary endpoint is to determine the safety, feasibility, and tolerability of combining paclitaxel with weekly bavituximab therapy. Secondary endpoints include pharmacodynamics and coagulation marker changes. Patients will also be assessed for ORR rate and median PFS according to RECIST criteria.

For further information about bavituximab trials conducted by Peregrine and its investigators, please visit <a href="http://www.peregrinetrials.com">http://www.peregrinetrials.com</a> or <a href="http://www.peregrinetrials.gov/ct2/results?term=bavituximab">http://www.peregrinetrials.com</a> or <a href="http://www.peregrinetrials.gov/ct2/results?term=bavituximab">http://www.peregrinetrials.com</a> or <a href="http://www.peregrinetrials.gov/ct2/results?term=bavituximab">http://www.peregrinetrials.com</a> or <a href="http://www.peregrinetrials.gov/ct2/results?term=bavituximab">http://www.peregrinetrials.gov/ct2/results?term=bavituximab</a>.

<sup>&</sup>lt;sup>1</sup> Loesch, D. et al (2002). *Journal of Clinical Oncology*.

#### **About Breast Cancer**

The World Health Organization reports that breast cancer is the most commonly diagnosed cancer in women and is second only to lung cancer as a leading cause of female cancer deaths. The National Cancer Institute estimates that approximately 230,480 U.S. women will be diagnosed with breast cancer and 39,520 will die from this disease in 2011. HER2-negative accounts for approximately 75% of metastatic breast cancers.

#### **About Bavituximab**

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.

#### **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(R). 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 outside customers. Additional information about Peregrine can be found at <a href="https://www.peregrineinc.com">www.peregrineinc.com</a>.

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 future advanced breast cancer trials will not be consistent with results experienced with this Phase II trial, the risk that results from the future trials may not support registration filings with the U.S. Food and Drug Administration, and the risk that Peregrine may not have or raise adequate financial resources to complete the planned clinical programs. 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 the quarterly report on Form 10-Q for the quarter ended July 31, 2011. The company cautions investors not to place undue reliance on the forward-looking statements contai

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