

# PEREGRINE PHARMACEUTICALS INC

## FORM 8-K (Current report filing)

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

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 12, 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 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION**

On December 12, 2011, Peregrine Pharmaceuticals, Inc. issued a press release to report the Company's financial results for the second quarter ended October 31, 2011. A copy of the press release is attached to this current report on Form 8-K as Exhibit 99.1. No additional information is included in this Current Report on Form 8-K.

The information included in this Current Report on Form 8-K, including the exhibit hereto, shall not be deemed "filed" for purposes of, nor shall it be deemed incorporated by reference in, any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such a filing.

## **ITEM 7.01 REGULATION FD DISCLOSURE**

On December 12, 2011, at 4:30 p.m. ET/1:30 p.m. PT, the Company hosted a conference call to discuss its second quarter fiscal year 2012 financial results. The webcast of the conference call will be archived on the Company's website for approximately 30 days.

## **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 12, 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 12, 2011

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

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**EXHIBIT INDEX**

<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
99.1	Press Release issued December 12, 2011

**Contact:**

Amy Figueroa or Jay Carlson  
 Peregrine Pharmaceuticals  
 (800) 987-8256  
 info@peregrineinc.com

**PEREGRINE PHARMACEUTICALS REPORTS SECOND QUARTER 2012 FINANCIAL RESULTS AND RECENT DEVELOPMENTS**

*-- Patient Enrollment Complete in 3 Randomized Phase II Bavituximab Trials with  
 Multiple Near-Term Data Milestones --*

TUSTIN, CA, December 12, 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 financial results for the second quarter ended October 31, 2011 of fiscal year (FY) 2012 and provided an update on its advancing clinical pipeline and other corporate developments.

“The last quarter was truly remarkable for our clinical pipeline. During the quarter we completed patient enrollment in three randomized Phase II bavituximab trials setting the stage for numerous clinical data points from those trials, with most expected in the first half of next year. We have already seen the first promising data from these trials, a 50% improvement in overall response rates based on a preliminary analysis of data for front-line non-small cell lung cancer patients treated with bavituximab with chemotherapy versus chemotherapy alone,” said Steven W. King, president and chief executive officer of Peregrine. “Across our bavituximab trials, the clinical data have been remarkably consistent with promising overall response rates and patient survival, and we are excited to see additional data from the three randomized studies as well as five additional bavituximab oncology trials which are underway. Importantly, our revenue-generating business Avid Bioservices has continued to serve its third-party clients and we are increasing our contract manufacturing revenue guidance to \$12-14 million for fiscal year 2012, versus \$10-12 million previously. Taken together we are seeing quite a few positive developments at Peregrine and look forward to updating you on progress as milestones are reached.”

**ONCOLOGY PROGRAM HIGHLIGHTS**
**Bavituximab Phase II NSCLC Trials**

Peregrine has completed patient enrollment in two randomized Phase II clinical trials in non-small cell lung cancer (NSCLC). Preliminary results from the 86-patient front-line NSCLC trial show a 50% improvement in overall tumor response rates (ORR). Patients treated with bavituximab plus carboplatin and paclitaxel currently demonstrate an ORR of 39%, versus 26% in patients treated with carboplatin and paclitaxel alone. Peregrine expects to report the trial’s secondary endpoints, median progression-free survival (PFS) and overall survival (OS), once these data are reached during 2012.

The second trial is a randomized, placebo-controlled, double-blinded trial in 121 second-line NSCLC patients evaluating bavituximab in combination with docetaxel versus placebo plus docetaxel. The study is expected to be unblinded in the first half of 2012 to assess the trial’s primary endpoint, overall response rates, according to RECIST criteria.

**Bavituximab Phase II Pancreatic Cancer Trial**

Patient enrollment is progressing in a randomized Phase II trial in up to 70 advanced pancreatic cancer patients evaluating bavituximab plus gemcitabine. Patient enrollment is expected to be complete with interim data reported during 2012.

**Bavituximab Phase II Breast Cancer Data**

Peregrine recently reported median OS data of 23.2 months from a single-arm Phase II trial evaluating bavituximab plus carboplatin and paclitaxel in 46 patients. Previously Peregrine reported ORR of 74% and median PFS of 6.9 months. All three data points compare favorably to a separate published study (Loesch, D. et al, 2002, Journal of Clinical Oncology) using a similar chemotherapy regimen of carboplatin and paclitaxel in a similar patient population showing ORR of 62%, median PFS of 4.8 months and median OS of 16.0 months.

### **Bavituximab Investigator-Sponsored Trials (IST)**

Patient enrollment is progressing in four ISTs evaluating bavituximab plus standard therapies in patients with HER-2 negative advanced metastatic breast cancer, advanced NSCLC, advanced liver cancer, and castration resistant advanced prostate cancer. These trials are designed to explore bavituximab's broad potential in additional treatment combinations and oncology indications.

### **Cotara® Clinical Program**

Peregrine's single-administration approach to treating recurrent glioblastoma multiforme (GBM) has shown encouraging 9.3 month median overall survival data from a Phase II trial in 41 patients. Peregrine has requested a meeting with the FDA and in response the Agency has agreed to provide written feedback on the company's proposed pivotal trial design. Peregrine's goal in this ongoing dialogue is to negotiate a trial which can be executed in 2 years or less in this orphan indication. Once a final protocol has been negotiated, Peregrine intends to seek partners both in the U.S. and internationally to support the development of Cotara for deadly GBM.

### **ANTIVIRAL PROGRAM HIGHLIGHTS**

#### **Bavituximab Phase II HCV Program**

In September 2011, Peregrine announced completion of patient enrollment in a randomized Phase II trial evaluating bavituximab plus ribavirin versus pegylated interferon alpha-2A plus ribavirin in 66 treatment-naïve patients infected with genotype-1 HCV. The trial's primary endpoint, 12-week early virologic response (EVR), is expected to be reported by early 2012.

### **PRECLINICAL DEVELOPMENT HIGHLIGHTS**

#### **Tumor Imaging**

In September 2011, Peregrine and affiliated researchers presented data at the Annual World Molecular Imaging Congress, further supporting the ability of the company's proprietary phosphatidylserine (PS)-targeting antibodies and antibody fragments to image tumors and assess the effectiveness of standard cancer therapies.

In November 2011, Peregrine presented data at the AACR/NCI/EORTC Conference on International Molecular Targets and Cancer Therapeutics demonstrating PS-targeting antibodies' ability to image breast, lung and prostate tumors as well as small metastatic growths.

#### **Infectious Disease**

In November 2011, researchers presented data at the Annual Chemical and Biologic Defense Science and Technology Conference demonstrating the ability of Peregrine's PS-targeting antibodies to localize to cells infected with Yersinia Pestis, the bacteria that causes plague, a U.S. category A biodefense pathogen.

#### **Intellectual Property**

During the second quarter of FY 2012, Peregrine's phospholipid-targeting patent portfolio was further strengthened by antiviral patents granted in several countries, including Japan, Korea and countries within the European Union. These patents cover treating all viruses and viral diseases using all antibodies that target PS and phosphatidylethanolamine (PE).

### **FINANCIAL RESULTS**

Total revenues for the second quarter of FY 2012 were \$4,232,000, compared to \$4,671,000 for the same quarter of the prior fiscal year, primarily attributable to lower government contract revenue due to the expiration of a former government contract during April 2011 of the prior fiscal year. Contract manufacturing revenue generated by Peregrine's biomanufacturing subsidiary Avid Bioservices was \$4,154,000 for the second quarter of FY 2012, compared to \$3,627,000 for the same quarter of the prior fiscal year. Based on the committed projects scheduled for Avid's third-party clients during the second half of FY 2012, Peregrine is increasing its guidance for contract manufacturing revenue to between \$12 and \$14 million for FY 2012, compared to previous guidance of between \$10 and \$12 million. Avid will also continue to utilize available capacity and resources to begin preparing for the future clinical development and potential commercialization of bavituximab and Cotara, while also seeking to grow its services to third-party clients.

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Total costs and expenses in the second quarter of FY 2012 were \$16,268,000, compared to \$13,049,000 in the second quarter of FY 2011. The increase primarily was attributable to higher research and development expenses to advance Peregrine's four randomized Phase II bavituximab clinical trials. For the second quarter FY 2012, research and development expenses were \$9,818,000, compared to \$7,344,000 for the second quarter of FY 2011.

Peregrine's consolidated net loss was \$12,055,000, or \$0.16 per share, for the second quarter of FY 2012, compared to a net loss of \$7,513,000 or \$0.13 per share, for the same quarter of the prior year. Peregrine reported \$18,055,000 in cash and cash equivalents at October 31, 2011, compared to \$16,540,000 at July 31, 2011.

More detailed financial information and analysis may be found in Peregrine's Quarterly Report on Form 10-Q, which will be filed with the Securities and Exchange Commission today.

### **Conference Call**

Peregrine will host a conference call and webcast today, December 12, 2011, at 4:30 PM ET (1:30 PM PT).

-- To listen to the conference call, please dial (877) 312-5443 or (253) 237-1126 and request the Peregrine Pharmaceuticals call. A replay of the call will be available starting approximately two hours after the conclusion of the call through December 26, 2011 by calling (855) 859-2056, or (404) 537-3406 and using passcode 28585204.

-- To listen to the live webcast, or access the archived webcast, please visit: <http://ir.peregrineinc.com/events.cfm>

### **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<sup>®</sup>. 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 the company may experience delays in reporting data from clinical trials, the risk that the results of the Phase II clinical trials may not correlate with the results from prior clinical and preclinical studies, the risk that the company may not have or be able to raise sufficient financial resources to complete the Phase II trials, the risk that Avid's revenue growth may slow or decline, the risk that Avid may experience technical difficulties in processing customer orders which could delay delivery of products to customers and receipt of payment, and the risk that one or more existing Avid customers terminates its contract prior to completion. 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 the company's SEC reports including, but not limited to, the annual report on Form 10-K for the fiscal 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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**PEREGRINE PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>THREE MONTHS ENDED</b>		<b>SIX MONTHS ENDED</b>	
	<b>OCTOBER 31,</b>		<b>OCTOBER 31,</b>	
	<b>2011</b>	<b>2010</b>	<b>2011</b>	<b>2010</b>
	<i>Unaudited</i>	<i>Unaudited</i>	<i>Unaudited</i>	<i>Unaudited</i>
<b>REVENUES :</b>				
Contract manufacturing revenue	\$ 4,154,000	\$ 3,627,000	\$ 9,593,000	\$ 4,610,000
Government contract revenue	-	966,000	-	3,077,000
License revenue	78,000	78,000	294,000	193,000
Total revenues	4,232,000	4,671,000	9,887,000	7,880,000
<b>COSTS AND EXPENSES :</b>				
Cost of contract manufacturing	3,718,000	3,003,000	6,735,000	4,159,000
Research and development	9,818,000	7,344,000	17,578,000	14,411,000
Selling, general and administrative	2,732,000	2,702,000	5,661,000	5,200,000
Total costs and expenses	16,268,000	13,049,000	29,974,000	23,770,000
<b>LOSS FROM OPERATIONS</b>	<b>(12,036,000)</b>	<b>(8,378,000)</b>	<b>(20,087,000)</b>	<b>(15,890,000)</b>
<b>OTHER INCOME (EXPENSE):</b>				
Interest and other income	9,000	996,000	22,000	1,014,000
Interest and other expense	(28,000)	(131,000)	(82,000)	(332,000)
<b>NET LOSS</b>	<b>\$ (12,055,000)</b>	<b>\$ (7,513,000)</b>	<b>\$ (20,147,000)</b>	<b>\$ (15,208,000)</b>
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:</b>				
Basic and Diluted	77,523,005	56,761,412	74,089,786	55,559,493
<b>BASIC AND DILUTED LOSS PER COMMON SHARE</b>	<b>\$ (0.16)</b>	<b>\$ (0.13)</b>	<b>\$ (0.27)</b>	<b>\$ (0.27)</b>

**PEREGRINE PHARMACEUTICALS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>OCTOBER 31, 2011</b>	<b>APRIL 30, 2011</b>
	<i>Unaudited</i>	
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 18,055,000	\$ 23,075,000
Trade and other receivables, net	1,191,000	1,389,000
Government contract receivables	-	93,000
Inventories, net	3,178,000	5,284,000
Prepaid expenses and other current assets, net	1,125,000	974,000
Total current assets	23,549,000	30,815,000
Property, net	2,540,000	2,209,000
Other assets	1,187,000	1,742,000
<b>TOTAL ASSETS</b>	<b>\$ 27,276,000</b>	<b>\$ 34,766,000</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 4,425,000	\$ 4,046,000
Accrued clinical trial and related fees	2,222,000	2,292,000
Accrued payroll and related costs	1,523,000	1,455,000
Notes payable, current portion and net of discount	333,000	1,321,000
Deferred revenue	2,012,000	5,617,000
Customer deposits	1,703,000	1,759,000
Other current liabilities	1,117,000	1,189,000
Total current liabilities	13,335,000	17,679,000
Deferred revenue	601,000	632,000
Other long-term liabilities	844,000	1,037,000
Commitments and contingencies		
<b>STOCKHOLDERS' EQUITY:</b>		
Preferred stock-\$0.001 par value; authorized 5,000,000 shares; non-voting; nil shares outstanding	-	-
Common stock-\$0.001 par value; authorized 325,000,000 shares; outstanding – 82,638,201 and 69,837,142, respectively	82,000	70,000
Additional paid-in capital	328,566,000	311,353,000
Accumulated deficit	(316,152,000)	(296,005,000)
Total stockholders' equity	12,496,000	15,418,000
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 27,276,000</b>	<b>\$ 34,766,000</b>

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