



September 9, 2013

## **Peregrine Pharmaceuticals Reports First Quarter Fiscal Year 2014 Financial Results and Recent Developments**

### **Bavituximab Pivotal Phase III Lung Cancer Trial Named "SUNRISE" on Track for Initiation by Calendar Year-End; Bavituximab Pre-Clinical Proof-Of Concept Studies Underway to Support Potential Immunotherapy Combination Trial; Avid Bioservices Quarterly Revenue Tops \$4.5 Million**

TUSTIN, CA -- (Marketwired) -- 09/09/13 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM), a biopharmaceutical company developing first-in-class monoclonal antibodies focused on the treatment and diagnosis of cancer, today announced financial results for the first quarter of fiscal year (FY) 2014 ended July 31, 2013 and provided an update on its advancing clinical pipeline and other corporate developments.

"We continue to steadily progress the bavituximab clinical program as we prepare to initiate a global Phase III trial by year-end in second-line non-small cell lung cancer. In addition to Phase III preparations, our researchers and external collaborators have undertaken a flurry of preclinical experimentation that will help guide exciting new combinations and therapeutic areas for bavituximab. This activity was spurred on by recent data showing that bavituximab works by harnessing the body's natural immune system to fight cancer," said Steven W. King, president and chief executive officer of Peregrine. "Our preclinical development plan is designed to simultaneously look at new indications and therapeutic regimens including new combinations with other immunotherapy agents. Because bavituximab acts on a primary immune system checkpoint, there are an abundance of possible immunotherapy combinations with agents working on further downstream targets. We expect results from these studies over the coming months as we move toward advancing new combinations into the clinic. We look forward to a number of updates on the program as we move through the rest of the year."

#### **BAVITUXIMAB ONCOLOGY PROGRAM HIGHLIGHTS**

##### **Lead Indication in Second-Line Non-Small Cell Lung Cancer:**

- Continued to plan for the initiation of the SUNRISE Trial (**Stimulating ImmUne RespoNse thRough BavItuximab in a PhaSE III Lung Cancer Study**).
  - SUNRISE is a Phase III, global, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety, tolerability and efficacy of bavituximab in patients with second-line non-small cell lung cancer (NSCLC). Specifically, the trial will evaluate bavituximab plus docetaxel versus docetaxel plus placebo in approximately 600 patients at clinical sites worldwide. Patients with Stage IIIb/IV non-squamous, NSCLC who have progressed after standard front-line treatment are eligible for enrollment. Patients will be randomized into 1 of 2 treatment arms. All patients will receive up to six 21-day cycles of docetaxel at 75 milligrams per meter squared plus weekly infusions of either bavituximab (3mg/kg) or placebo until progression of toxicity. The primary endpoint of the trial will be overall survival. The company anticipates initiating the SUNRISE trial by the end of this calendar year.

##### **Other Oncology Indications:**

The company is exploring the potential of bavituximab through a number of investigator-sponsored trials (IST) including:

- A Phase I IST evaluating bavituximab in combination with paclitaxel in up to 14 patients with HER2-negative metastatic breast cancer. All patients have been enrolled in this trial with interim data on 13 evaluable patients presented at the 2013 American Society of Clinical Oncology (ASCO) Annual Meeting showing that 85% of patients achieved an objective tumor response, including 15% of patients achieving a complete response measured in accordance with RECIST criteria.
- A Phase I/II IST evaluating bavituximab in combination with sorafenib in up to 48 patients with advanced hepatocellular carcinoma (liver cancer). The Phase I portion of the trial has completed patient enrollment with enrollment in the Phase II portion of the trial ongoing.
- A Phase Ib IST evaluating bavituximab in combination with carboplatin and pemetrexed in up to 25 patients with previously untreated Stage IV NSCLC. This trial continues to enroll and dose patients.

- A Phase I IST evaluating bavituximab in combination with capecitabine and radiation therapy in up to 18 patients with Stage II or III rectal adenocarcinoma. This trial continues to enroll and dose patients.

## BAVITUXIMAB IMMUNOTHERAPY DEVELOPMENT PROGRAM

This morning, Peregrine announced the publication of a data supporting the immune-stimulatory mechanism of action of phosphatidylserine (PS)-targeting antibodies, such as the company's lead drug candidate bavituximab in the American Association for Cancer Research (AACR) peer-reviewed journal, *Cancer Immunology Research*. In the manuscript titled: "Phosphatidylserine-targeting antibody induces M1 macrophage polarization and promotes myeloid derived suppressor cell differentiation," researchers demonstrated that exposed PS plays a major role in the inhibition of pro-inflammatory cellular and cytokine responses in tumors and that PS-targeting antibodies override this primary upstream immune checkpoint, activating multiple downstream immunostimulatory effects, including the conversion of myeloid derived suppressor cells into tumor immunity promoting M1 macrophages and the generation of tumor killing cytotoxic T-cells.

Peregrine is exploring the potential to combine bavituximab with other immunotherapies such as anti-CTLA-4, anti-PD-1, and anti-PD-L1 antibodies and has initiated several ongoing pre-clinical proof-of-concept studies to support an immunotherapy combination trial with bavituximab.

## IMAGING PROGRAM HIGHLIGHTS

### PS-Targeting Molecular Imaging Program

Peregrine continues to enroll and dose patients in an open-label, single-center trial of its experimental PS-targeting molecular imaging candidate, 124I-PGN650, in patients with various solid tumor types. The primary goal of the trial is to estimate radiation dosimetry in critical and non-critical organs. Secondary objectives of the trial are tumor imaging and safety.

## FINANCIAL RESULTS

"Our wholly-owned contract manufacturing subsidiary, Avid Bioservices, continue to perform well, generating over \$4.5 million in contract manufacturing revenue in the first quarter of FY 2014, a non-dilutive source of capital. With our current backlog for services, we expect contract manufacturing revenue for the entire FY 2014 to be between \$18 and \$22 million," said Paul Lytle, chief financial officer of Peregrine. "We also remained focused on seeking potential partners for our bavituximab program while successfully maintaining a balanced financial approach that provides us much flexibility in our ongoing partnering discussions."

Total revenues for the first quarter of FY 2014 were \$4,688,000, compared to \$4,251,000 for the same quarter of the prior fiscal year. The increase was primarily attributed to an increase in contract manufacturing revenue generated from Avid Bioservices due to an increase in the number of completed manufacturing runs.

Contract manufacturing revenues from Avid's clinical and commercial biomanufacturing services provided to its third-party clients for the first quarter FY 2014 were \$4,581,000, compared to \$4,135,000 for the same quarter of the prior fiscal year. Peregrine expects contract manufacturing revenues for FY 2014 to be between \$18 million and \$22 million. In addition to providing biomanufacturing services to its third-party clients, Avid will continue to utilize available capacity and resources to continue its preparation for later stage clinical development and potential commercialization of bavituximab and Cotara.

Total costs and expenses in the first quarter of FY 2014 were \$12,308,000, compared to \$11,922,000 in the first quarter of FY 2013. This increase was attributable to the current year three-month period increase in the cost of contract manufacturing associated with higher revenues in the current quarter combined with an increase in selling, general and administrative expenses. The increase in selling, general and administrative expenses for the first quarter FY 2014 compared to the first quarter of FY 2013 was primarily attributable to increases in share-based compensation expense, payroll and related expenses, and corporate legal fees.

Peregrine's consolidated net loss was \$7,600,000, or \$0.05 per share, for the first quarter of FY 2014, compared to a net loss of \$7,664,000, or \$0.07 per share, for the same quarter of the prior year.

Peregrine reported \$41,600,000 in cash and cash equivalents as of July 31, 2013, compared to \$35,204,000 at fiscal year ended April 30, 2013.

More detailed financial information and analysis may be found in Peregrine's Annual 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 this afternoon, September 9, 2013, at 4:30 PM EDT (1:30 PM PDT).

To listen to the conference call, please dial (877) 312-5443 or (253) 237-1126 and request the Peregrine Pharmaceuticals conference call. A replay of the call will be available starting approximately two hours after the conclusion of the call through September 16, 2013 by calling (855) 859-2056, or (404) 537-3406 and using passcode 37006614.

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

**About Peregrine Pharmaceuticals, Inc.**

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company with a portfolio of innovative monoclonal antibodies in clinical trials focused on the treatment and diagnosis of cancer. The company is pursuing multiple clinical programs in cancer with its lead immunotherapy 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 third-party 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 the company may not be able to initiate the Phase III trial within its anticipated timeline, the risk that the results from the Phase III trial may not support a future Biologics License Application (BLA) submission, the risk that the company may not have or raise adequate financial resources to complete the Phase III trial, the risk that the company may not find a suitable partner for the Phase III trial or the PS program, the risk that the results from ongoing proof-of-concept studies may not support combining bavituximab with other antibodies that enhance tumor immunity, such as an anti-PD1, anti-PD-L1, or anti-CTLA-4, the risk that such combination studies may not result in any additional benefit, 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 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, 2013 and our quarterly report on Form 10-Q for the quarter ended July 31, 2013. 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.

**PEREGRINE PHARMACEUTICALS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

	<b>THREE MONTHS ENDED</b>	
	<b>July 31, 2013</b>	<b>July 31, 2012</b>
	<i>Unaudited</i>	<i>Unaudited</i>
<b>REVENUES:</b>		
Contract manufacturing revenue	\$ 4,581,000	\$ 4,135,000
License revenue	107,000	116,000
Total revenues	<u>4,688,000</u>	<u>4,251,000</u>
<b>COSTS AND EXPENSES:</b>		
Cost of contract manufacturing	2,670,000	2,024,000
Research and development	5,304,000	6,981,000
Selling, general and administrative	4,334,000	2,917,000
Total costs and expenses	<u>12,308,000</u>	<u>11,922,000</u>
<b>LOSS FROM OPERATIONS</b>	<u>(7,620,000)</u>	<u>(7,671,000)</u>
<b>OTHER INCOME (EXPENSE):</b>		
Interest and other income	21,000	8,000
Interest and other expense	<u>(1,000)</u>	<u>(1,000)</u>
<b>NET LOSS</b>	<u>\$ (7,600,000)</u>	<u>\$ (7,664,000)</u>

<b>COMPREHENSIVE LOSS</b>	\$ (7,600,000 )	\$ (7,664,000 )
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING</b>		
Basic and diluted	149,393,630	103,283,937
<b>BASIC AND DILUTED LOSS PER COMMON SHARE</b>	\$ (0.05 )	\$ (0.07 )

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

	<u>JULY 31,</u> <u>2013</u>	<u>APRIL 30,</u> <u>2013</u>
	<i>Unaudited</i>	
<b>ASSETS</b>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 41,600,000	\$ 35,204,000
Trade and other receivables, net	2,272,000	1,662,000
Inventories	5,679,000	4,339,000
Prepaid expenses and other current assets, net	635,000	709,000
Total current assets	50,186,000	41,914,000
Property and equipment, net	2,448,000	2,678,000
Other assets	689,000	466,000
<b>TOTAL ASSETS</b>	<u>\$ 53,323,000</u>	<u>\$ 45,058,000</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
CURRENT LIABILITIES:		
Accounts payable	\$ 2,160,000	\$ 2,821,000
Accrued clinical trial and related fees	608,000	930,000
Accrued payroll and related costs	3,271,000	3,582,000
Deferred revenue, current portion	4,164,000	4,171,000
Customer deposits	8,528,000	8,059,000
Other current liabilities	1,335,000	998,000
Total current liabilities	20,066,000	20,561,000
Deferred revenue, less current portion	292,000	292,000
Other long-term liabilities	422,000	445,000
Commitments and contingencies		
STOCKHOLDERS' EQUITY:		
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 - 153,506,811 and 143,768,946, respectively	153,000	143,000
Additional paid-in capital	407,894,000	391,521,000
Accumulated deficit	(375,504,000 )	(367,904,000 )
Total stockholders' equity	32,543,000	23,760,000
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u>\$ 53,323,000</u>	<u>\$ 45,058,000</u>

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Source: Peregrine Pharmaceuticals

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