



July 14, 2014

## **Peregrine Pharmaceuticals Reports Fourth Quarter and Year-End Fiscal Year 2014 Financial Results and Recent Developments**

### **SUNRISE Phase III Trial Initiated at Over 100 Sites Worldwide; Launch of First Baviximab Immunotherapy Trial Combining Upstream and Downstream Checkpoint Inhibitors in Advanced Melanoma; Avid's Contract Manufacturing Revenue Tops \$22 Million for Fiscal Year 2014**

TUSTIN, CA -- (Marketwired) -- 07/14/14 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM) (NASDAQ: PPHMP), a biopharmaceutical company focused on the development of first-in-class monoclonal antibodies for the treatment and diagnosis of cancer, today announced financial results for the fourth quarter and the fiscal year (FY) 2014 ended April 30, 2014 and provided an update on its advancing clinical pipeline and other corporate developments.

"Our overall strategy is focused on advancing the baviximab clinical program, engaging with potential partners, clinicians and researchers that can help expand potential indications and combinations for baviximab while we continue to prepare for commercial activities and work toward maintaining the revenue growth seen for our wholly-owned biomanufacturing subsidiary, Avid Bioservices," said Steven W. King, president and chief executive officer of Peregrine. "This past quarter we made significant progress in this strategy by expanding the baviximab Phase III SUNRISE trial which now has over 100 open sites, assisting in the launch of the first immunotherapy combination trial that will evaluate the therapeutic potential of combining baviximab with Yervoy® in patients with advanced melanoma and another solid revenue quarter at Avid of over \$6M. These activities, along with ongoing and expanded research efforts exploring new combinations for baviximab, continue to set the stage for exciting developments over the coming year."

#### **BAVIXIMAB ONCOLOGY PROGRAM HIGHLIGHTS**

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

The company continues to actively open additional trial sites worldwide and enroll patients in the SUNRISE (Stimulating Immune Response through Baviximab in a Phase III Lung Cancer Study) Phase III Trial. SUNRISE is a Phase III, global, randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety, tolerability and efficacy of baviximab as a second-line treatment in patients with non-small cell lung cancer (NSCLC). The trial is evaluating baviximab plus the standard chemotherapy docetaxel versus docetaxel plus placebo in approximately 600 patients at more than 100 clinical sites worldwide. Patients with Stage IIIb/IV non-squamous, NSCLC who have progressed after standard front-line treatment are eligible for enrollment. Patients are being randomized into 1 of 2 treatment arms. All patients are receiving up to six 21-day cycles of docetaxel at 75 milligrams per meter squared plus weekly infusions of either baviximab (3mg/kg) or placebo until progression or toxicity. The primary endpoint of the trial is overall survival. As of today, over 100 sites worldwide have been initiated in this pivotal trial.

For additional information about the SUNRISE trial please visit [www.sunrisetrial.com](http://www.sunrisetrial.com) or [ClinicalTrials.gov](http://ClinicalTrials.gov) using the Identifier NCT01999673.

##### **Clinical Data that Supports New Baviximab Oncology Indications:**

The company is currently evaluating opportunities to advance the clinical development of baviximab in breast cancer, based on promising data from a Phase I investigator-sponsored trial (IST) that evaluated baviximab in combination with paclitaxel in 13 patients with HER2-negative metastatic breast cancer including approximately half of the patients that were classified as "triple negative," a traditionally difficult-to-treat patient population. Encouraging interim data from patients that received the treatment combination was 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 as measured in accordance with RECIST criteria.

"The promising results from the Phase I breast cancer trial that were presented at ASCO in 2013 are currently being finalized in a manuscript that I anticipate publishing in the near future," said Alison Stopeck, MD, Professor of Medicine and Director, Clinical Breast Cancer Program at the University of Arizona Cancer Center, Tucson, Arizona. "Based on the encouraging results observed in this trial, including both a favorable safety profile as well as prolonged clinical responses, I believe that additional clinical development is warranted in this indication."

## Exploring Additional Bavituximab Indications through Investigator-Sponsored Trials (IST):

A Phase I/II IST evaluating bavituximab in combination with sorafenib in up to 48 patients with advanced hepatocellular carcinoma (liver cancer).

A Phase Ib IST evaluating bavituximab in combination with carboplatin and pemetrexed in up to 25 patients with previously untreated Stage IV NSCLC.

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.

## BAVITUXIMAB IMMUNOTHERAPY DEVELOPMENT PROGRAM

Through this program, Peregrine continues to explore the potential of combining bavituximab with other immunotherapies, experimental checkpoint inhibitors as well as vaccines. The company has initiated multiple proof-of-concept studies and presented encouraging preclinical data that could support new trials as well as serving as a basis for the ongoing Phase Ib immunotherapy combination trial. Presentation of data from the Phase Ib trial, as well as preclinical and proof-of-concept studies are anticipated throughout fiscal year 2015.

During the quarter, the company announced the first clinical trial to emerge from this program with the initiation of an IST of bavituximab in combination with Bristol-Myers Squibb's ipilimumab (Yervoy®), for the treatment of advanced melanoma. This is an open-label, randomized, single-center Phase Ib trial in up to 24 patients. Data from preclinical studies evaluating the combination in a model of melanoma yielded an enhanced anti-tumor activity compared to ipilimumab alone.

During the quarter, data was presented at two Keystone Symposia and the Annual Meeting of the American Association for Cancer Research (AACR) from studies validating the immune-stimulatory mechanism of action of bavituximab. These presentations showed that the combination of a preclinical phosphatidylserine (PS)-targeting antibody and the immune checkpoint inhibitors anti-CTLA-4 or anti-PD-1 antibodies yielded superior anti-tumor immune responses in animal models of melanoma and colon cancer compared to anti-CTLA-4 and PD-1 antibodies alone. In a separate study, an equivalent antibody to *bavituximab* administered with stereotactic body radiation therapy demonstrated 100% improvement in survival and favorable tumor eradication in a model of non-small cell lung cancer compared to irradiation alone. In the antiviral area, researchers presented data showing that a PS-binding antibody inhibited HIV infection of cells by blocking viral receptors used by HIV for cell entry.

## PS-TARGETING MOLECULAR IMAGING PROGRAM

The company is exploring the potential of its experimental PS-targeting molecular imaging candidate, 124I-PGN650, in patients with various solid tumor types. This is an open-label, single-center trial with a primary goal of estimating radiation dosimetry in critical and non-critical organs and secondary objectives of tumor imaging and safety.

## AVID BIOSERVICES

"Avid Bioservices had a strong fourth quarter and record year generating over \$6 million in contract manufacturing revenue in the fourth quarter of FY 2014 and over \$22 million in contract manufacturing revenue for the full FY 2014," said Paul Lytle, chief financial officer of Peregrine. "We have also continued to strengthen our cash position over the past fiscal year to over \$78 million as of June 30, 2014 as we continue to advance the Phase III SUNRISE trial and prepare for the potential commercialization of bavituximab. Under the company's hybrid business model, Avid is evaluating manufacturing options that would create new manufacturing capacity for the potential commercial launch of bavituximab while also providing Avid with available capacity for its continued growth."

## FINANCIAL RESULTS

Total revenues for the fourth quarter of FY 2014 were \$6,474,000, compared to \$4,254,000 for the same quarter of the prior fiscal year. For FY 2014, total revenues were \$22,401,000, compared to \$21,683,000 for the prior year. The FY 2014 increase was primarily attributed to an increase in contract manufacturing revenue generated from Avid Bioservices.

Contract manufacturing revenues from Avid's clinical and commercial biomanufacturing services provided to its third-party clients were \$22,294,000 for FY 2014 compared to \$21,333,000 for FY 2013. Current contract manufacturing commitments from Avid's third-party customers are in excess of \$26 million, covering services to be provided during FY 2015 and into FY 2016. Based on these current commitments, Peregrine expects contract manufacturing revenues for FY 2015 to be between \$19 and \$23 million. In addition to providing biomanufacturing services to its third-party clients, Avid will continue to support the potential commercialization of bavituximab.

Total costs and expenses in the fourth quarter of FY 2014 were \$17,003,000, compared to \$12,717,000 in the fourth quarter of FY 2013. For FY 2014, total costs and expenses were \$58,107,000 compared to \$50,035,000 for FY 2013. This increase was primarily attributable to current year increases in research and development expenses and selling, general and administrative expenses. The increase in research and development expenses for FY 2014 compared to FY 2013 was primarily attributable to expenses associated with the preparation and initiation of our Phase III SUNRISE trial combined with an increase in share-based compensation expense (non-cash). The increase in selling, general and administrative expenses for FY 2014 compared to FY 2013 was primarily attributable to increases in share-based compensation expense (non-cash), payroll and related expenses and corporate legal fees. For the fourth quarter FY 2014, research and development expenses were \$8,813,000, compared to \$5,835,000 for the fourth quarter of FY 2013, and for FY 2014 were \$27,723,000, compared to \$24,306,000 for FY 2013. For the fourth quarter FY 2014, selling, general and administrative expenses were \$4,361,000, compared to \$3,665,000 for the fourth quarter of FY 2013 and for FY 2014 were \$17,274,000 compared to \$13,134,000 for FY 2013.

Peregrine's consolidated net loss attributable to common stockholders was \$10,649,000, or \$0.06 per share, for the fourth quarter of FY 2014, compared to a net loss attributable to common stockholders of \$8,449,000, or \$0.06 per share, for the same quarter of the prior year. For FY 2014, net loss attributable to common stockholders was \$35,763,000, or \$0.22 per share, compared to \$29,780,000, or \$0.25 per share, for FY 2013.

Peregrine reported \$77,490,000 in cash and cash equivalents as of April 30, 2014, compared to \$35,204,000 at fiscal year ended April 30, 2013. As of June 30, 2014, the company reported \$78,331,000 in cash and cash equivalents.

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

### **Conference Call**

Peregrine will host a conference call and webcast this afternoon, July 14, 2014, 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 July 21, 2014 by calling (855) 859-2056, or (404) 537-3406 and using passcode 66161283.

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 pipeline of novel drug candidates in clinical trials for the treatment and diagnosis of cancer. The company's lead immunotherapy candidate, bavituximab, is in Phase III development for the treatment of second-line non-small lung cancer (the "SUNRISE trial") along with several investigator-sponsored trials evaluating other treatment combinations and additional oncology indications. The company is also advancing a molecular imaging agent, 124I-PGN650, in an exploratory clinical trial for the imaging of multiple solid tumor types. 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 experience delays in the enrollment of patients in the Phase III SUNRISE trial and may not achieve its anticipated enrollment timeline, the risk that the results from the Phase III SUNRISE 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 SUNRISE trial, the risk that the company may not find a suitable partner for the bavituximab or Cotara programs, the risk that data from pre-clinical studies and early stage clinical trials, including ISTs, may not correlate with the results of later stage clinical 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 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, 2014 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.

Yervoy is a registered trademark of Bristol-Meyers Squibb.

**PEREGRINE PHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

	<i>Three Months Ended April 30,</i>		<i>Twelve Months Ended April 30,</i>	
	<i>2014</i>	<i>2013</i>	<i>2014</i>	<i>2013</i>
	<i>Unaudited</i>	<i>Unaudited</i>		
<b>REVENUES:</b>				
Contract manufacturing revenue	\$ 6,474,000	\$ 4,176,000	\$ 22,294,000	\$ 21,333,000
License revenue	-	78,000	107,000	350,000
Total revenues	<u>6,474,000</u>	<u>4,254,000</u>	<u>22,401,000</u>	<u>21,683,000</u>
<b>COSTS AND EXPENSES:</b>				
Cost of contract manufacturing	3,829,000	3,217,000	13,110,000	12,595,000
Research and development	8,813,000	5,835,000	27,723,000	24,306,000
Selling, general and administrative	4,361,000	3,665,000	17,274,000	13,134,000
Total costs and expenses	<u>17,003,000</u>	<u>12,717,000</u>	<u>58,107,000</u>	<u>50,035,000</u>
<b>LOSS FROM OPERATIONS</b>	<u>(10,529,000)</u>	<u>(8,463,000)</u>	<u>(35,706,000)</u>	<u>(28,352,000)</u>
<b>OTHER INCOME (EXPENSE):</b>				
Interest and other income	281,000	15,000	349,000	322,000
Interest and other expense	-	(1,000)	(5,000)	(54,000)
Loss on early extinguishment of debt	-	-	-	(1,696,000)
<b>NET LOSS</b>	<u>\$ (10,248,000)</u>	<u>\$ (8,449,000)</u>	<u>\$ (35,362,000)</u>	<u>\$ (29,780,000)</u>
<b>COMPREHENSIVE LOSS</b>	<u>\$ (10,248,000)</u>	<u>\$ (8,449,000)</u>	<u>\$ (35,362,000)</u>	<u>\$ (29,780,000)</u>
Series E preferred stock accumulated dividends	(401,000)	-	(401,000)	-
<b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>	<u>\$ (10,649,000)</u>	<u>\$ (8,449,000)</u>	<u>\$ (35,763,000)</u>	<u>\$ (29,780,000)</u>
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:</b>				
Basic and Diluted	<u>177,264,434</u>	<u>137,872,343</u>	<u>161,579,649</u>	<u>120,370,333</u>
<b>BASIC AND DILUTED LOSS PER COMMON SHARE</b>	<u>\$ (0.06)</u>	<u>\$ (0.06)</u>	<u>\$ (0.22)</u>	<u>\$ (0.25)</u>

**PEREGRINE PHARMACEUTICALS, INC.**

**CONSOLIDATED BALANCE SHEETS**

**AS OF APRIL 30, 2014 AND 2013**

	<u>2014</u>	<u>2013</u>
<b>ASSETS</b>		

**CURRENT ASSETS:**

Cash and cash equivalents	\$ 77,490,000	\$ 35,204,000
Trade and other receivables, net	1,332,000	1,662,000
Inventories	5,530,000	4,339,000
Prepaid expenses and other current assets, net	1,419,000	709,000
Total current assets	85,771,000	41,914,000

**PROPERTY AND EQUIPMENT:**

Leasehold improvements	1,538,000	1,383,000
Laboratory equipment	5,646,000	5,441,000
Furniture, fixtures, office equipment and software	2,679,000	2,627,000
	9,863,000	9,451,000
Less accumulated depreciation and amortization	(7,416,000)	(6,773,000)
Property and equipment, net	2,447,000	2,678,000
Other assets	2,327,000	466,000
<b>TOTAL ASSETS</b>	<b>\$ 90,545,000</b>	<b>\$ 45,058,000</b>

**LIABILITIES AND STOCKHOLDERS' EQUITY****CURRENT LIABILITIES:**

Accounts payable	\$ 2,434,000	\$ 2,821,000
Accrued clinical trial and related fees	4,433,000	930,000
Accrued payroll and related costs	3,837,000	3,582,000
Deferred revenue, current portion	5,241,000	4,171,000
Customer deposits	5,760,000	8,059,000
Other current liabilities	502,000	998,000
Total current liabilities	22,207,000	20,561,000

Deferred revenue, less current portion	292,000	292,000
Other long-term liabilities	347,000	445,000

Commitments and contingencies

**STOCKHOLDERS' EQUITY:**

Preferred stock - \$.001 par value; authorized 5,000,000 shares; issued and outstanding - 775,000 and nil, respectively	1,000	-
Common stock - \$.001 par value; authorized 325,000,000 shares; issued and outstanding - 178,871,164 and 143,768,946, respectively	179,000	143,000
Additional paid-in-capital	470,785,000	391,521,000
Accumulated deficit	(403,266,000)	(367,904,000)
Total stockholders' equity	67,699,000	23,760,000

<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 90,545,000</b>	<b>\$ 45,058,000</b>
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