

# Peregrine Pharmaceuticals Reports Fourth Quarter and Fiscal Year 2013 Financial Results and Recent Developments

Positive Phase IIb Data in Second-Line NSCLC and FDA Agreement on Pivotal Phase III Trial Design Position Start of Phase III Trial by Calendar Year-End; Bavituximab's Immunotherapeutic Mechanism of Action Data Presented at AACR Creates Expanded Drug Development Opportunities; Avid's Contract Manufacturing Revenue Topped \$21 Million for FY 2013 and Starts FY 2014 With Over \$27 Million in Revenue Backlog From Contract Manufacturing Business

TUSTIN, CA -- (Marketwired) -- 07/11/13 -- 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 fourth quarter and fiscal year (FY) ended April 30, 2013 and provided an update on its advancing clinical pipeline and other corporate developments.

"The combination of preclinical data supporting bavituximab's immunotherapeutic mechanism of action presented at AACR, compelling second-line NSCLC data presented at ASCO and reaching the recent agreement with the FDA on a pivotal Phase III design have helped transform our bavituximab clinical program. We are now focused on initiating this Phase III trial in second-line NSCLC by the end of the year while simultaneously evaluating new areas of opportunity based on the enhanced understanding we now have of bavituximab's mechanism of action," said Steven W. King, president and chief executive officer of Peregrine. "This increased knowledge further supports the combination with docetaxel that we are pursuing in Phase III while opening the door to multiple new potential combinations that were not previously explored. These developments have initiated new partnering opportunities as well as increased interest amongst current partnership discussions surrounding the bavituximab program which continue while we execute this supplemental development strategy."

Data from a series of preclinical studies exploring the mechanism of action for phosphatidylserine (PS)-targeting antibodies, such as bavituximab, were presented at the Annual Meeting of the American Association for Cancer Research (AACR). Results from these studies demonstrated that PS-targeting antibodies mediate immune-stimulatory changes in tumors by acting on upstream immune checkpoints and transforming those immune cells that are inhibiting immune recognition (MDSC's) into tumor-fighting (M1) macrophages and activated dendritic cells that lead to the formation of tumor fighting T-cells. Based on these findings, Peregrine is collecting immune correlative data from three of the its ongoing investigator-sponsored clinical trials in breast, rectal and liver cancers while also exploring the potential to combine bavituximab with other immunotherapies such as PD-1 antibodies and CTLA-4 targeted approaches.

## **BAVITUXIMAB ONCOLOGY PROGRAM HIGHLIGHTS**

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

- Reached agreement with the U.S. Food and Drug Administration (FDA) on a Phase III registration trial design of bavituximab in second-line non-small cell lung cancer (NSCLC).
- Recently announced final results from its 121 patient Phase IIb randomized, double-blind, placebo-controlled trial of bavituximab in second-line NSCLC at the 2013 American Society of Clinical Oncology (ASCO) Annual Meeting.
  - Promising 60% improvement in median overall survival (OS) in the 3mg/kg bavituximab plus docetaxel arm compared to the control arm and bavituximab was well-tolerated with no significant differences in adverse events between the trial arms.
  - Subgroup analyses of OS by key patient characteristics including age, gender, ECOG status, ethnicity and prior treatment favored the bavituximab 3 mg/kg arm.
- Planning for the initiation of a pivotal Phase III trial by calendar year-end.

## Other Oncology Indications:

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

 A Phase II randomized, open-label, clinical trial evaluating bavituximab plus gemcitabine in 70 patients with previously untreated, advanced Stage IV pancreatic cancer. Data presented at the 2013 ASCO Annual Meeting showed a more than a doubling of overall response rate (ORR) in the bavituximab-containing arm, a positive safety profile and a modest improvement in median OS. As enrollment included patients with poor prognosis including advanced metastatic disease with significant liver involvement and poor performance status associated with rapid disease progression, a subgroup analysis was conducted. Results from this subgroup analysis showed that the effect of bavituximab plus gemcitabine was more pronounced in patients with ECOG ≤ 1 and those without hepatic metastases. While the final data combined with the results from subgroup analyses warrant future consideration, given the fast progression of pancreatic cancer and the need for longer treatment periods associated with immunotherapies such as bavituximab, there are no plans to initiate a follow-on trial in pancreatic cancer at this time.

- A Phase II randomized, open-label clinical trial evaluating bavituximab plus carboplatin and paclitaxel versus carboplatin and paclitaxel (C/P) alone in up to 86 patients with previously untreated Stage IIIb or Stage IV NSCLC. Data recently announced, with less than 60% of survival events reached, that while the bavituximab-containing treatment arm demonstrated a median OS of over 14 months, there was not a meaningful enough difference in survival between the two arms of the trial to support another study using this combination and timing of therapy. An independent study with another immunotherapy agent showed that when C/P are given together with an immunotherapy, as was done in this bavituximab trial, the results were similar to the control arm however when C/P are administered in advance of the immunotherapy much more favorable results are achieved. We are currently evaluating options for moving bavituximab forward in front-line NSCLC. Full results from this trial will be presented at a future scientific meeting or through publication.
- A Phase I IST evaluating bavituximab in combination with paclitaxel in up to 14 patients with HER2-negative metastatic
  breast cancer. Interim data on 13 evaluable patients were presented at the 2013 ASCO Annual Meeting showed that
  85% of patients achieved an objective tumor response, including 15% of patients achieving a complete response (CR)
  measured in accordance with RECIST criteria. All patients have been enrolled in this trial.
- 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.

#### **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. Recently, data were presented from imaging studies demonstrating that the chemotherapeutic drug docetaxel, a commonly prescribed second-line treatment for patients with advanced NSCLC, increases the exposure of bavituximab's target molecule, PS, on tumor blood vessel cells and tumor cells. Results also showed that PS exposure in tumors is correlated with tumor burden and response to docetaxel treatment, supporting exposed PS as a promising biomarker of cancer and response to therapy. In the June 2013 issue of the journal Molecular Imaging, scientists from Peregrine published results from a study showing that PGN650 could be useful in imaging tumors and detect enhanced PS exposure in response to chemotherapy.

#### FINANCIAL RESULTS

"This quarter capped off a record year for our wholly-owned manufacturing subsidiary, Avid Bioservices, which generated over \$21 million in non-dilutive contract manufacturing revenue and has started FY 2014 with more than \$27 million in committed services from existing third-party clients," said Paul Lytle, chief financial officer of Peregrine. "We have also strengthened our cash position that gives us the needed flexibility to initiate the upcoming Phase III trial in second-line NSCLC while we continue to evaluate our future opportunities."

Total revenues for the fourth quarter of FY 2013 were \$4,254,000, compared to \$2,065,000 for the same quarter of the prior fiscal year. For FY 2013, total revenues were \$21,683,000, compared to \$15,233,000 for the prior year. The FY 2013 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 increased 44% to \$21,333,000 for FY 2013, which were the highest reported amount in Avid's history and were within Peregrine's previous guidance range, compared to \$14,783,000 for FY 2012. FY 2014 started with manufacturing commitments from Avid's third-party customers in excess of \$27 million, covering services to be provided during FY 2014 and into FY 2015. Of this amount, 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 fourth quarter of FY 2013 were \$12,717,000, compared to \$12,955,000 in the fourth quarter of FY 2012. For FY 2013, total costs and expenses were \$50,035,000 compared to \$57,303,000 for FY 2012. This decrease primarily was attributable to lower research and development expenses due to the decrease in clinical trial expenses. For the fourth quarter FY 2013, research and development expenses were \$5,835,000, compared to \$8,930,000 for the fourth quarter of FY 2012, and for FY 2013 were \$24,306,000, compared to \$35,688,000 for FY 2012. Selling, general and administrative expenses for FY 2013 were \$13,134,000 compared to \$11,462,000 for FY 2012.

Peregrine's consolidated net loss was \$8,449,000, or \$0.06 per share, for the fourth quarter of FY 2013, compared to a net loss of \$10,882,000 or \$0.10 per share, for the same quarter of the prior year. For FY 2013, net loss was \$29,780,000, or \$0.25 per share, compared to \$42,119,000, or \$0.50 per share, for FY 2012.

Peregrine reported \$35,204,000 in cash and cash equivalents as of April 30, 2013, compared to \$18,033,000 at fiscal year ended April 30, 2012. As of June 30, 2013, the company had \$42,563,000 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 11, 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 July 18, 2013 by calling (855) 859-2056, or (404) 537-3406 and using passcode 10642041.

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. (<a href="www.avidbio.com">www.avidbio.com</a>), which provides development and biomanufacturing services for both Peregrine and third-party customers. Additional information about Peregrine can be found at <a href="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 forwardlooking 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 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. 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.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

Three Months Ended April 30,

Twelve Months Ended April 30,

2013 2012

2013 2012

		Unaudited		Unaudited				
REVENUES:								
Contract manufacturing revenue	\$	4,176,000	\$	1,987,000	\$	21,333,000	\$	14,783,000
License revenue	_	78,000	_	78,000	_	350,000	_	450,000
Total revenues		4,254,000		2,065,000		21,683,000		15,233,000
COSTS AND EXPENSES:								
Cost of contract manufacturing		3,217,000		934,000		12,595,000		10,153,000
Research and development		5,835,000		8,930,000		24,306,000		35,688,000
Selling, general and administrative	_	3,665,000		3,091,000		13,134,000		11,462,000
Total costs and expenses	_	12,717,000	_	12,955,000	_	50,035,000	_	57,303,000
LOSS FROM OPERATIONS	_	(8,463,000)	_	(10,890,000)		(28,352,000)	_	(42,070,000)
OTHER INCOME (EXPENSE):								
Interest and other income		15,000		10,000		322,000		41,000
Interest and other expense		(1,000)		(2,000)		(54,000)		(90,000)
Loss on early extinguishment of debt	_	<u>-</u>	_	<u>-</u>	_	(1,696,000)	_	<u>-</u>
NET LOSS	\$	(8,449,000)	\$	(10,882,000)	\$	(29,780,000)	\$	(42,119,000)
COMPREHENSIVE LOSS	\$	(8,449,000)	\$	(10,882,000)	\$	(29,780,000)	\$	(42,119,000)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:								
Basic and Diluted	_	137,872,343	_	99,303,678	_	120,370,333	_	83,572,761
BASIC AND DILUTED LOSS PER COMMON SHARE	\$	(0.06)	\$_	(0.10)	\$	(0.25)	\$	(0.50)

PEREGRINE PHARMACEUTICALS, INC. CONSOLIDATED BALANCE SHEETS AS OF APRIL 30, 2013 AND 2012

	2013		2012		
ASSETS					
CURRENT ASSETS:					
Cash and cash equivalents	\$	35,204,000	\$	18,033,000	
Trade and other receivables, net		1,662,000		2,353,000	
Inventories		4,339,000		3,611,000	
Prepaid expenses and other current assets, net		709,000		795,000	
Total current assets		41,914,000		24,792,000	
PROPERTY:					
Leasehold improvements		1,383,000		1,383,000	
Laboratory equipment		5,441,000		4,967,000	
Furniture, fixtures, office equipment and software	_	2,627,000		2,287,000	
		9,451,000		8,637,000	
Less accumulated depreciation and amortization	_	(6,773,000)		(5,737,000)	
Property, net		2,678,000		2,900,000	
Other assets		466,000		570,000	
TOTAL ASSETS	<u>\$</u>	45,058,000	\$	28,262,000	

PEREGRINE PHARMACEUTICALS, INC.
CONSOLIDATED BALANCE SHEETS
AS OF APRIL 30, 2013 AND 2012 (continued)

2013 2012

LIABILITIES AND STOCKHOLDERS' EQUITY

**CURRENT LIABILITIES:** 

Accounts payable	\$	2,821,000	5	\$	3,492,000
Accrued clinical trial and related fees		930,000			2,111,000
Accrued payroll and related costs		3,582,000			2,468,000
Deferred revenue, current portion		4,171,000			3,651,000
Customer deposits		8,059,000			4,865,000
Other current liabilities		998,000			1,052,000
Total current liabilities		20,561,000			17,639,000
Deferred revenue, less current portion		292,000			361,000
Other long-term liabilities		445,000			779,000
Commitments and contingencies					
STOCKHOLDERS' EQUITY:					
Preferred stock - \$.001 par value; authorized 5,000,000 shares; non-voting; none issued		-			-
Common stock - \$.001 par value; authorized 325,000,000 shares;					
outstanding - 143,768,946 and 101,421,365, respectively		143,000			101,000
Additional paid-in-capital		391,521,000			347,506,000
Accumulated deficit		(367,904,000)			(338,124,000)
Total stockholders' equity	_	23,760,000		_	9,483,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	45,058,000	<u> </u>	\$	28,262,000

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