

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

Interim Data Show Doubling of Median Overall Survival in Bavituximab-Treated Patients from Double-Blind, Placebo-Controlled Phase II Trial in Second-Line Non-Small Cell Lung Cancer; Recent Data Strongly Support Advancing Bavituximab Program Into Phase III Clinical Development

TUSTIN, CA -- (Marketwire) -- 09/10/12 -- 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 ended July 31, 2012 of fiscal year (FY) 2013 and provided an update on its advancing clinical pipeline and other corporate developments.

"We have achieved major milestones since the end of last quarter with the unblinding of our proof-of-principle bavituximab study in second-line NSCLC in May and the recent announcement of overall survival data from the study being the most significant. The statistically significant overall survival seen in that study is an obvious green light for us to begin plans to advance the program into Phase III and goes a long way toward validating the technology platform," said Steven W. King, president and chief executive officer of Peregrine. "Following these exciting developments, the upcoming milestones for the program include additional clinical data from eight ongoing bavituximab clinical trials, an end of Phase II meeting with the FDA expected by year end, and potential partnership as the result of ongoing discussions. This is truly an exciting time at Peregrine and we look forward to advancing the bavituximab program as well as the rest of our business operations."

#### BAVITUXIMAB ONCOLOGY PROGRAM HIGHLIGHTS

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

Last week, in a late-breaker, oral plenary presentation at the 2012 Chicago Multidisciplinary Symposium in Thoracic Oncology meeting, interim data was presented from a randomized, double-blind, placebo-controlled Phase IIb trial evaluating two dose levels of bavituximab (bavituximab-containing arms) plus docetaxel versus docetaxel plus placebo (control arm) in second-line Stage IIIb/IV non-small cell lung cancer (NSCLC). This trial enrolled 121 patients with second-line Stage IIIb or Stage IV non-squamous NSCLC following one prior chemotherapy regimen and patients were equally randomized to 1 of the 3 treatment arms, with 117 of the enrolled patients being evaluable per the clinical protocol. Patients received up to 6 cycles of docetaxel (75mg/m2) plus either placebo, 1 mg/kg bavituximab, or 3 mg/kg bavituximab until disease progression. Recent data from the trial showed a doubling of median overall survival (OS) in both bavituximab-containing arms compared to the control arm and a statistically significant improvement in overall survival. In addition, bavituximab continues to be well-tolerated. Given the magnitude of this data, Peregrine is preparing for an End-of-Phase II meeting with the U.S. Food and Drug Administration (FDA) by the end of calendar year 2012 that should allow us to initiate Phase III by mid-2013.

"The unique immune directed attack of bavituximab and preliminary survival advantage of far greater magnitude than what has been observed historically with anti-angiogenesis agents provide potentially yet another example of clinically relevant immune directed therapy moving forward," said John Nemunaitis, M.D., executive director of the Mary Crowley Cancer Research Centers and an investigator in Peregrine's Phase II bavituximab second-line NSCLC clinical trial.

## Additional Bavituximab Clinical Trials

Peregrine currently has seven additional ongoing clinical trials as follows:

- A randomized, open-label, Phase II clinical trial evaluating bavituximab plus carboplatin and paclitaxel versus carboplatin and paclitaxel alone in 83 evaluable patients with previously untreated Stage IIIb or Stage IV NSCLC patients completed enrollment in September of 2011 and the event-driven median overall survival data will be available upon maturation.
- A randomized, open-label, Phase II clinical trial evaluating bavituximab plus gemcitabine versus gemcitabine alone in 70 patients with previously untreated Stage IV pancreatic cancer completed enrollment in June 2012. The primary endpoint, median OS, is an event-driven endpoint and will be reported once reached.
- Phase I/II Investigator Sponsored Trial (IST) investigating bavituximab in combination with sorafenib in patients with advanced hepatocellular carcinoma (liver cancer). The Phase I portion of the trial has completed patient enrollment.
- A Phase I/II IST evaluating bavituximab in combination with cabazitaxel in patients with second-line castration-resistant

prostate cancer.

- A Phase Ib IST evaluating bavituximab in combination with carboplatin and pemetrexed in patients with previously untreated Stage IV NSCLC.
- A Phase I IST evaluating bavituximab in combination with paclitaxel in up to 14 patients with HER2-negative metastatic breast cancer.
- A Phase I IST evaluating bavituximab in combination with capecitabine and radiation therapy in patients with Stage II or III
  rectal adenocarcinoma.

#### COTARA PROGRAM HIGHLIGHTS

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 and the FDA continue to advance discussions surrounding the negotiation of a pivotal trial design. The company plans to seek partners both in the U.S. and internationally to support the development of Cotara for this deadly form of brain cancer.

#### **IMAGING PROGRAM HIGHLIGHTS**

PS-Targeting Molecular Imaging Program

In April 2012, Peregrine launched its experimental phosphatidylserine (PS)-targeting molecular imaging candidate, 1241-PGN650, into clinical development for the imaging of multiple 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. Patients are currently being enrolled in the trial.

## FINANCIAL RESULTS

Total revenues for the first quarter of FY 2013 were \$4,251,000, compared to \$5,655,000 for the same quarter of the prior fiscal year. This decrease was primarily attributable to lower contract manufacturing revenue generated by Peregrine's biomanufacturing subsidiary Avid Bioservices, which generated contract manufacturing revenue of \$4,135,000 for the first quarter of FY 2013, compared to \$5,439,000 for the same quarter of the prior fiscal year. The decrease in contract manufacturing revenue was primarily due to a decrease in the number of completed manufacturing runs released and shipped during the current quarter, which can be attributed to the timing of services provided to Avid's third-party clients. However, based on current manufacturing commitments from Avid's third-party clients for services to be provided during the remainder of FY 2013, we expect contract manufacturing revenue to be at least \$15 million for FY 2013. In addition, 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, while also seeking to grow its services from third-party clients.

Total costs and expenses decreased \$1,784,000 to \$11,922,000 in the first quarter of FY 2013 from \$13,706,000 in the first quarter of FY 2012. This decrease was primarily attributable to lower contract manufacturing costs incurred by Avid combined with lower research and development expenses associated with lower clinical trial costs. For the first quarter of FY 2013, cost of contract manufacturing and research and development expenses were \$2,024,000 and \$6,981,000, respectively, compared to \$3,017,000 and \$7,760,000, respectively, for the first quarter of FY 2012. Selling, general and administrative expenses for the first quarter of FY 2013 were \$2,917,000 and were in-line with the first quarter of FY 2012.

Peregrine's consolidated net loss was \$7,664,000, or \$0.07 per basic and diluted share, for the first quarter of FY 2013, compared to a net loss of \$8,092,000, or \$0.11 per basic and diluted share, for the same quarter of the prior year.

Peregrine reported \$18,991,000 in cash and cash equivalents at July 31, 2012, compared to \$18,033,000 at April 30, 2012. Subsequent to July 31, 2012, Peregrine announced that it had secured a \$30 million term loan from Oxford Finance, MidCap Financial, and Silicon Valley Bank. Under the loan agreement, the company received initial funding of \$15 million upon closing on August 30, 2012, and has an option to receive an additional \$15 million, provided, on or before March 31, 2013, Peregrine meets certain predefined milestones, as described in loan agreement.

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 this morning, September 10, 2012, at 11:00 AM ET (8:00 AM 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 24, 2012 by calling (855) 859-2056, or (404) 537-3406 and using passcode 27367274

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

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 product 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 outside 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 overall survival data from the randomized, double-blind, placebo-controlled Phase IIb together with other earlier reported data from the trial may not support registration filings with the U.S. Food and Drug Administration, the risk that overall survival data from the planned Phase III trial will not be consistent with the results from the randomized Phase IIb trial, the risk that results from the other randomized Phase Il trial will not be consistent with results experienced in the earlier single-arm Phase II trial or support registration filings with the FDA, the risk that Peregrine may not have or raise adequate financial resources to complete the planned clinical programs... 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 and the risk that one or more existing Avid customers, including those [with committed manufacturing or representing its backlog], 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 forwardlooking 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 our SEC reports including, but not limited to, the annual report on Form 10-K for the fiscal year ended April 30, 2012 and quarterly report on Form 10-Q for the quarter ended July 31, 2012. 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

	THREE MONTHS ENDED		
	<b>J</b> u:	ly 31, 2012	July 31, 2011
		Unaudited	Unaudited
REVENUES:			
Contract manufacturing revenue	\$	4,135,000	\$ 5,439,000
License revenue		116,000	216,000
Total revenues		4,251,000	5,655,000

# COSTS AND EXPENSES:

Cost of contract manufacturing	2,024,000	3,017,000
Research and development	6,981,000	7,760,000
Selling, general and administrative	2,917,000	2,929,000
Total costs and expenses		13,706,000
LOSS FROM OPERATIONS	(7,671,000)	(8,051,000)
OTHER INCOME (EXPENSE):		
Interest and other income	8,000	13,000
Interest and other expense	(1,000)	(54,000)
NET LOSS	\$ (7,664,000)	\$ (8,092,000)
	========	========
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING		
Basic and diluted	103,283,937	70,656,568
	========	========
BASIC AND DILUTED LOSS PER COMMON SHARE	\$ (0.07)	\$ (0.11)
COMPREHENSIVE LOSS	\$ (7,664,000)	\$ (8,092,000)

# CONDENSED CONSOLIDATED BALANCE SHEETS

	JULY 31, 2012			APRIL 30,	
			2012		
		Unaudited			
ASSETS					
CURRENT ASSETS:					
Cash and cash equivalents	\$	18,991,000	\$	18,033,000	
Trade and other receivables, net		2,271,000		2,353,000	
Inventories, net		5,744,000		3,611,000	
Prepaid expenses and other current assets,					
net		887,000		795,000	
Total current assets		27,893,000		24,792,000	
Property, net		2,868,000		2,900,000	
Other assets		745,000		570,000	
TOTAL ASSETS	\$	31,506,000	\$	28,262,000	
	==	=======	==	=======	
LIABILITIES AND STOCKHOLDERS' EQUITY					
CURRENT LIABILITIES:					
Accounts payable	\$	4,151,000	\$	3,492,000	
Accrued clinical trial and related fees		1,909,000		2,111,000	
Accrued payroll and related costs		2,908,000		2,468,000	
Deferred revenue		6,056,000		3,651,000	
Customer deposits		10,224,000		4,865,000	
Other current liabilities		1,308,000		1,052,000	
Total current liabilities		26,556,000		17,639,000	

Deferred revenue	284,000	361,000
Other long-term liabilities	742,000	779,000
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 - 104,178,431		
and 101,421,365, respectively	104,000	101,000
Additional paid-in capital	349,608,000	347,506,000
Accumulated deficit	(345,788,000)	(338,124,000)
Total stockholders' equity	3,924,000	9,483,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 31,506,000	\$ 28,262,000

# Contact:

Christopher Keenan or Jay Carlson

Peregrine Pharmaceuticals, Inc.

(800) 987-8256

info@peregrineinc.com

Source: Peregrine Pharmaceuticals

News Provided by Acquire Media