

# Peregrine Pharmaceuticals Reports First Quarter Fiscal Year 2015 Financial Results and Recent Developments

SUNRISE Phase III Lung Cancer Trial Operational at Over 130 Sites Worldwide; Preclinical Data in Breast Cancer Supports Immuno-Oncology Combinations With Bavituximab; Clinical Data From Liver, Breast and Front-Line Non-Small Lung Cancer Trials Anticipated in the Coming Months; Enrollment Complete in Bavituximab Plus Sorafenib Investigator-Sponsored Trial in Patients With Advanced Liver Cancer; Company Delivers Solid First Quarter With \$5.5 Million in Contract Manufacturing Revenue

TUSTIN, CA -- (Marketwired) -- 09/09/14 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM) (NASDAQ: PPHMP), a biopharmaceutical company developing first-in-class monoclonal antibodies for the treatment and diagnosis of cancer, today announced financial results for the first quarter of fiscal year (FY) 2015 ended July 31, 2014 and provided an update on its advancing clinical pipeline led by its investigational immuno-oncology candidate bavituximab and reviewed other corporate developments.

"We continued to advance the bavituximab clinical program on multiple fronts with the major focus on executing the SUNRISE Phase III trial which is progressing well with the initiation of new global clinical sites bringing the total participating sites to over 130. In addition, our collaborator at UT Southwestern recently completed enrollment in an important liver cancer study opening the door for data from this study as well as other bavituximab clinical trials to be presented over the coming months," said Steven W. King, president and chief executive officer of Peregrine. "In addition to the clinical trial activities, we have a robust preclinical collaboration program evaluating new combinations and dosing strategies combining bavituximab with chemotherapy, radiation and immune-oncology approaches that are constantly yielding important data that will help guide and expand the clinical program."

# BAVITUXIMAB ONCOLOGY PROGRAM HIGHLIGHTS

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

The company continues to actively open trial sites worldwide and enroll patients in the SUNRISE (**S**timulating Imm**U**ne Respo**N**se th**R**ough Bav/tuximab in a Pha**SE** III Lung Cancer Study) Phase III Trial. SUNRISE is a Phase III, randomized, doubleblind, placebo-controlled clinical trial designed to evaluate the safety, tolerability and efficacy of bavituximab as a second-line treatment in patients with non-small cell lung cancer (NSCLC). The trial is evaluating bavituximab plus the standard chemotherapy 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 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 bavituximab (3mg/kg) or placebo until progression or toxicity. The primary endpoint of the trial is overall survival. As of today, over 130 sites worldwide have been initiated in this pivotal trial.

For additional information about the SUNRISE trial please visit <u>www.sunrisetrial.com</u> or <u>ClinicalTrials.gov</u> using the Identifier NCT01999673.

Clinical Data that Supports New Bavituximab Oncology Indications:

The company is currently evaluating opportunities to advance the clinical development of bavituximab in breast cancer. Final data from a Phase I investigator-sponsored trial (IST) that evaluated bavituximab in combination with paclitaxel in 13 patients with HER2-negative metastatic breast cancer are anticipated to be published in a manuscript in the near future.

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) has completed enrollment of the Phase II portion and data from this trial are expected to be presented at an upcoming conference.

"The Phase II portion of this trial has completed enrollment with a number of patients currently on treatment, the longest of

whom has been on treatment for 18 months," said Adam Yopp, M.D. Assistant Professor of Surgery at the University of Texas Southwestern Medical Center's Simmons Cancer Center. "While the results from this trial are preliminary, I believe they are promising. I am excited about this potential combination given the new understandings about bavituximab's mechanism and I look forward to sharing the full set of data from this Phase II trial at a future scientific conference."

A Phase Ib IST evaluating bavituximab in combination with carboplatin and pemetrexed in up to 25 patients with previously untreated Stage IV NSCLC has completed enrollment with interim data accepted for presentation at the 2014 Chicago Multidisciplinary Symposium in Thoracic Oncology to be held October 30 - November 1, 2014.

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 is open for patient enrollment.

A Phase Ib IST evaluating bavituximab in combination with Bristol-Myers Squibb's ipilimumab (Yervoy®) in up to 24 patients with advanced melanoma is open for patient enrollment.

### BAVITUXIMAB IMMUNO-ONCOLOGY DEVELOPMENT PROGRAM

This program continues to explore the potential of combining bavituximab with other immunotherapies, experimental immunooncology drugs including checkpoint inhibitors, as well as vaccines. Recently, data presented at ImVacS, The Annual Immunotherapies and Vaccine Summit shows that the combination of a PS-targeting antibody equivalent to bavituximab administered with an anti-PD-1 antibody displays statistically significant tumor growth suppression while also demonstrating a significant increase in tumor-fighting T-cells into the tumor microenvironment compared to anti-PD-1 antibody treatment alone in an immune competent animal model of breast cancer.

Data from the company's immuno-oncology program, as well as clinical translational data aimed at assessing and measuring

changes in immune response pre- and post-treatment from the liver cancer IST will be the subject of presentations at the 29<sup>th</sup> Annual Meeting of the Society for the Immunotherapy of Cancer (SITC) to be held November 6-9, 2014.

#### 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 started the fiscal year on a strong note generating \$5.5 million in contract manufacturing revenue for the first quarter," said Paul Lytle, chief financial officer of Peregrine. "In addition, Avid has been successful in expanding its client roster while also continuing to evaluate manufacturing options that would create new manufacturing capacity for the potential commercial launch of bavituximab in addition to providing Avid with increased capacity for its clients."

#### FINANCIAL RESULTS

Total revenues for the first quarter of FY 2015 were \$5,496,000, compared to \$4,688,000 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.

Contract manufacturing revenue from Avid's clinical and commercial biomanufacturing services provided to its third-party clients for the first quarter FY 2015 were \$5,496,000, compared to \$4,581,000 for the same quarter of the prior fiscal year. Peregrine expects contract manufacturing revenue 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 first quarter of FY 2015 were \$18,667,000, compared to \$12,308,000 in the first quarter of FY 2014. This increase was primarily attributable to current quarter increases in research and development expenses associated with the SUNRISE Phase III trial and incremental increases in selling, general and administrative expenses. For the first quarter FY 2015, research and development expenses were \$10,201,000, compared to \$5,304,000 for the first quarter of FY 2014. For the first quarter FY 2015, selling, general and administrative expenses were \$4,883,000, compared to \$4,334,000 for the first quarter of FY 2014.

Peregrine's consolidated net loss attributable to common stockholders was \$14,157,000, or \$0.08 per share, for the first quarter of FY 2015, compared to a net loss attributable to common stockholders of \$7,600,000, or \$0.05 per share, for the same quarter of the prior year.

Peregrine reported \$73,256,000 in cash and cash equivalents as of July 31, 2014 compared to \$77,490,000 at fiscal year ended April 30, 2014.

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 afternoon, September 9, 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 September 16, 2014 by calling (855) 859-2056, or (404) 537-3406 and using passcode 94131393.

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 inhouse cGMP manufacturing capabilities through its wholly-owned subsidiary Avid Bioservices, Inc. (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.

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 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.

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

		THREE MONTHS ENDED			
	July 31, 2014 Unaudited		July 31, 2013 Unaudited		
REVENUES:					
Contract manufacturing revenue	\$	5,496,000	\$	4,581,000	
License revenue		-		107,000	

Total revenues		5,496,000	_	4,688,000
COSTS AND EXPENSES:				
Cost of contract manufacturing		3,583,000		2,670,000
Research and development		10,201,000		5,304,000
Selling, general and administrative		4,883,000	_	4,334,000
Total costs and expenses		18,667,000	_	12,308,000
LOSS FROM OPERATIONS		(13,171,000)	_	(7,620,000)
OTHER INCOME (EXPENSE):				
Interest and other income		42,000		21,000
Interest and other expense		-	_	(1,000)
NET LOSS	\$	(13,129,000)	\$	(7,600,000)
COMPREHENSIVE LOSS	\$	(13,129,000)	\$	(7,600,000)
Series E preferred stock accumulated dividends		(1,028,000)		-
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$	(14,157,000)	\$	(7,600,000)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING		<u> </u>	==	· · · · · · · · · · · · · · · · · · ·
Basic and diluted		179,118,255		149,393,630
BASIC AND DILUTED LOSS PER COMMON SHARE	\$	(0.08)	\$	(0.05)
PEREGRINE PHARMACEUTICALS, INC.				
CONDENSED CONSOLIDATED BALANCE SHEETS				
		JULY 31, 2014		APRIL 30, 2014
		Unaudited		
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	\$	73,256,000	\$	77,490,000
Trade and other receivables, net		1,391,000		1,332,000
Inventories		5,998,000		5,530,000
	_	5,998,000 883,000	_	5,530,000 1,419,000
Inventories	_		_	
Inventories Prepaid expenses and other current assets, net		883,000	_	1,419,000
Inventories Prepaid expenses and other current assets, net Total current assets	_	883,000 81,528,000	_	1,419,000 85,771,000 2,447,000 2,327,000
Inventories Prepaid expenses and other current assets, net Total current assets Property and equipment, net	\$	883,000 81,528,000 3,647,000		1,419,000 85,771,000 2,447,000
Inventories Prepaid expenses and other current assets, net Total current assets Property and equipment, net Other assets TOTAL ASSETS <i>LIABILITIES AND STOCKHOLDERS' EQUITY</i>		883,000 81,528,000 3,647,000 2,432,000		1,419,000 85,771,000 2,447,000 2,327,000
Inventories Prepaid expenses and other current assets, net Total current assets Property and equipment, net Other assets TOTAL ASSETS <i>LIABILITIES AND STOCKHOLDERS' EQUITY</i> CURRENT LIABILITIES:		883,000 81,528,000 3,647,000 2,432,000 87,607,000	<u> </u>	1,419,000 85,771,000 2,447,000 2,327,000 90,545,000
Inventories Prepaid expenses and other current assets, net Total current assets Property and equipment, net Other assets TOTAL ASSETS <i>LIABILITIES AND STOCKHOLDERS' EQUITY</i>		883,000 81,528,000 3,647,000 2,432,000		1,419,000 85,771,000 2,447,000 2,327,000 90,545,000 2,434,000
Inventories Prepaid expenses and other current assets, net Total current assets Property and equipment, net Other assets TOTAL ASSETS <i>LIABILITIES AND STOCKHOLDERS' EQUITY</i> CURRENT LIABILITIES: Accounts payable		883,000 81,528,000 3,647,000 2,432,000 87,607,000 5,080,000	<u> </u>	1,419,000 85,771,000 2,447,000 2,327,000 90,545,000
Inventories Prepaid expenses and other current assets, net Total current assets Property and equipment, net Other assets TOTAL ASSETS <i>LIABILITIES AND STOCKHOLDERS' EQUITY</i> CURRENT LIABILITIES: Accounts payable Accrued clinical trial and related fees		883,000 81,528,000 3,647,000 2,432,000 87,607,000 5,080,000 1,887,000	<u> </u>	1,419,000 85,771,000 2,447,000 2,327,000 90,545,000 2,434,000 4,433,000
Inventories Prepaid expenses and other current assets, net Total current assets Property and equipment, net Other assets TOTAL ASSETS <i>LIABILITIES AND STOCKHOLDERS' EQUITY</i> CURRENT LIABILITIES: Accounts payable Accrued clinical trial and related fees Accrued payroll and related costs		883,000 81,528,000 3,647,000 2,432,000 87,607,000 5,080,000 1,887,000 2,654,000	<u> </u>	1,419,000 85,771,000 2,447,000 2,327,000 90,545,000 2,434,000 4,433,000 3,837,000
Inventories Prepaid expenses and other current assets, net Total current assets Property and equipment, net Other assets TOTAL ASSETS <i>LIABILITIES AND STOCKHOLDERS' EQUITY</i> CURRENT LIABILITIES: Accounts payable Accrued clinical trial and related fees Accrued payroll and related costs Deferred revenue, current portion		883,000 81,528,000 3,647,000 2,432,000 87,607,000 5,080,000 1,887,000 2,654,000 4,670,000	<u> </u>	$\begin{array}{r} 1,419,000\\ 85,771,000\\ 2,447,000\\ 2,327,000\\ 90,545,000\\ \end{array}$
Inventories Prepaid expenses and other current assets, net Total current assets Property and equipment, net Other assets TOTAL ASSETS <i>LIABILITIES AND STOCKHOLDERS' EQUITY</i> CURRENT LIABILITIES: Accounts payable Accrued clinical trial and related fees Accrued payroll and related costs Deferred revenue, current portion Customer deposits		883,000 81,528,000 3,647,000 2,432,000 87,607,000 5,080,000 1,887,000 2,654,000 4,670,000 6,226,000	<u> </u>	$\begin{array}{r} 1,419,000\\ 85,771,000\\ 2,447,000\\ 2,327,000\\ \hline 90,545,000\\ \hline \\ 2,434,000\\ 4,433,000\\ 3,837,000\\ 5,241,000\\ 5,760,000\\ \end{array}$
Inventories Prepaid expenses and other current assets, net Total current assets Property and equipment, net Other assets TOTAL ASSETS <i>LIABILITIES AND STOCKHOLDERS' EQUITY</i> CURRENT LIABILITIES: Accounts payable Accrued clinical trial and related fees Accrued payroll and related costs Deferred revenue, current portion Customer deposits Other current liabilities		883,000 81,528,000 3,647,000 2,432,000 87,607,000 5,080,000 1,887,000 2,654,000 4,670,000 6,226,000 606,000	<u> </u>	$\begin{array}{r} 1,419,000\\ 85,771,000\\ 2,447,000\\ 2,327,000\\ 90,545,000\\ \end{array}$
Inventories Prepaid expenses and other current assets, net Total current assets Property and equipment, net Other assets TOTAL ASSETS <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b> CURRENT LIABILITIES: Accounts payable Accrued clinical trial and related fees Accrued payroll and related costs Deferred revenue, current portion Customer deposits Other current liabilities Total current liabilities		883,000 81,528,000 3,647,000 2,432,000 87,607,000 5,080,000 1,887,000 2,654,000 4,670,000 6,226,000 606,000	<u> </u>	$\begin{array}{r} 1,419,000\\ 85,771,000\\ 2,447,000\\ 2,327,000\\ \hline 90,545,000\\ \hline 90,545,000\\ 4,433,000\\ 3,837,000\\ 5,241,000\\ 5,760,000\\ \hline 502,000\\ 22,207,000\\ \hline \end{array}$
Inventories Prepaid expenses and other current assets, net Total current assets Property and equipment, net Other assets TOTAL ASSETS <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b> CURRENT LIABILITIES: Accounts payable Accrued clinical trial and related fees Accrued payroll and related fees Accrued payroll and related costs Deferred revenue, current portion Customer deposits Other current liabilities Total current liabilities		883,000 81,528,000 3,647,000 2,432,000 87,607,000 1,887,000 2,654,000 4,670,000 6,226,000 606,000 21,123,000	<u> </u>	$\begin{array}{r} 1,419,000\\ 85,771,000\\ 2,447,000\\ 2,327,000\\ 90,545,000\\ \end{array}$
Inventories Prepaid expenses and other current assets, net Total current assets Property and equipment, net Other assets TOTAL ASSETS <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b> CURRENT LIABILITIES: Accounts payable Accrued clinical trial and related fees Accrued payroll and related fees Accrued payroll and related costs Deferred revenue, current portion Customer deposits Other current liabilities Total current liabilities Deferred revenue, less current portion Other long-term liabilities		883,000 81,528,000 3,647,000 2,432,000 87,607,000 1,887,000 2,654,000 4,670,000 6,226,000 606,000 21,123,000	<u> </u>	$\begin{array}{r} 1,419,000\\ 85,771,000\\ 2,447,000\\ 2,327,000\\ 90,545,000\\ \end{array}$
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Inventories Prepaid expenses and other current assets, net Total current assets Property and equipment, net Other assets TOTAL ASSETS LIABILITIES AND STOCKHOLDERS' EQUITY CURRENT LIABILITIES: Accounts payable Accrued clinical trial and related fees Accrued payroll and related costs Deferred revenue, current portion Customer deposits Other current liabilities Total current liabilities Deferred revenue, less current portion Other long-term liabilities STOCKHOLDERS' EQUITY: Preferred stock-\$0.001 par value; authorized 5,000,000 shares; issued and		883,000 81,528,000 3,647,000 2,432,000 87,607,000 1,887,000 2,654,000 4,670,000 6,226,000 606,000 21,123,000	<u> </u>	$\begin{array}{r} 1,419,000\\ 85,771,000\\ 2,447,000\\ 2,327,000\\ 90,545,000\\ \hline \\ 2,434,000\\ 4,433,000\\ 3,837,000\\ 5,241,000\\ 5,760,000\\ \hline \\ 502,000\\ 22,207,000\\ 292,000\\ 347,000\\ \end{array}$

Additional paid-in capital	481,807,000		470,785,000
Accumulated deficit	(416,395,000)	_	(403,266,000)
Total stockholders' equity	65,592,000	_	67,699,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 87,607,000	\$	90,545,000

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Source: Peregrine Pharmaceuticals

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