

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

SUNRISE Phase III Lung Cancer Trial for Peregrine's Lead Immuno-Oncology Candidate Bavituximab Operational at Over 150 Sites Worldwide; Data From Immuno-Oncology Development Program Shows Potential of Bavituximab to Significantly Enhance Checkpoint Inhibitors Anti-PD-1 and Anti-CTLA-4 in Multiple Preclinical Models; Avid Bioservices Announces Expansion of Manufacturing Capacity to Support the Potential Commercial Launch of Bavituximab and Growth of Contract Manufacturing Business

TUSTIN, CA -- (Marketwired) -- 12/10/14 -- Peregrine Pharmaceuticals, Inc. (NASDAQ: PPHM) (NASDAQ: PPHMP), a biopharmaceutical company focused on advancing bavituximab, a new immuno-oncology antibody targeting the highly immunosuppressive phosphatidylserine (PS) signaling pathway, towards commercialization and providing integrated cGMP clinical and commercial bio-manufacturing services, today announced financial results for the second quarter of fiscal year (FY) 2015 ended October 31, 2014. The company also provided an update on its advancing clinical pipeline and reviewed other corporate developments.

"Our product development activities are dedicated to bringing bavituximab, the lead clinical compound targeting the inhibitory PS signaling pathway, to the market in order to address the unmet medical needs of cancer patients," said Steven W. King, president and chief executive officer of Peregrine. "Our lead effort towards this goal is the advancement of our bavituximab Phase III SUNRISE trial in non-small cell lung cancer, which is now open for enrollment at over 150 centers worldwide, with an anticipated completion of enrollment by the end of calendar year 2015. We have also made great strides in exploring new oncology opportunities including promising immuno-oncology combinations pairing bavituximab with PD-1 and CTLA-4 targeting agents resulting in significant therapeutic improvements in multiple preclinical cancer models. The combination of immuno-oncology agents has the potential to completely change the treatment paradigm for cancer patients and we feel bavituximab is in an excellent position to be a significant player in future immuno-oncology combination treatment options. On the contract manufacturing side of our business, we continued to see solid performance with \$6.3 million in contract manufacturing revenues generated for the second quarter. We believe Avid has significant growth potential and in order to realize this, we are more than doubling our current biomanufacturing capacity."

The company's mission is to develop a brand new class of immunotherapies focused on the clinical advancement of our lead drug candidate bavituximab which targets the immunosuppressive PS signaling pathway. Bavituximab has the potential to be an effective part of treatment regimens in many different tumor types and has recently shown promise in combination with other immuno-oncology compounds. Over the past quarter, the company has made important progress in bringing this novel immunotherapy closer to the market led by the SUNRISE Phase III clinical trial.

The company has continued to open trial sites, now totaling over 150 worldwide, and to enroll patients in the SUNRISE (Stimulating ImmUne RespoNse thRough BavItuximab in a PhaSE III Lung Cancer Study) Phase III trial. SUNRISE is a Phase III, randomized, double-blind, 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. The primary endpoint of the trial is overall survival. For additional information about the SUNRISE trial, please visit www.sunrisetrial.com or ClinicalTrials.gov using the Identifier NCT01999673.

The company's commitment to exploring the full clinical potential of bavituximab in combination with chemotherapies or other immuno-oncology agents is being executed through a series of Investigator-Sponsored Trials (IST) in multiple solid tumor indications. The following represents anticipated upcoming data from ongoing or completed clinical studies as well as the status of trials that can yield data in the future:

- Final data from a Phase I IST that evaluated bavituximab in combination with paclitaxel in patients with HER2-negative metastatic breast cancer has been submitted for publication and the company is currently evaluating opportunities to advance the clinical development of bavituximab in breast cancer.
- Data from a Phase I/II IST that evaluated bavituximab in combination with sorafenib in patients with advanced

hepatocellular carcinoma (liver cancer) has been accepted for poster presentation at the 2015 Gastrointestinal Cancers Symposium to be held January 15-17, 2015 in San Francisco, California and for an oral presentation at the Society of Surgical Oncology's 68th Annual Cancer Symposium to be held March 25-28, 2015 in Houston, Texas.

- Data from a Phase Ib IST that evaluated bavituximab in combination with carboplatin and pemetrexed in patients with
  previously untreated Stage IV NSCLC was presented at the 2014 Chicago Multidisciplinary Symposium in Thoracic
  Oncology. In this single-arm trial, patients treated with bavituximab in combination with carboplatin and pemetrexed
  achieved an overall response rate (ORR) of 35%, a median progression free survival (PFS) of 4.8 months and a median
  overall survival (OS) of 12.2 months. Favorable trends in ORR and OS as well as tolerability continue to support the
  potential of bavituximab in 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 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.

As part of the company's mission to discover the full potential of its immunotherapy bavituximab in clinical disease applications, the company is advancing studies through its Immuno-Oncology Development Program. This program was designed to explore the potential of combining bavituximab with other immunotherapies, experimental immuno-oncology drugs including checkpoint inhibitors, as well as vaccines.

- Data was recently presented at the Cancer Research Institutes' (CRI) "Cancer Immunotherapy: Out of the Gate" and the
  Society for Immunotherapy of Cancer's (SITC) 29th Annual Meeting and Associated Programs conferences. Data from
  the conferences show that tumor growth was significantly slowed in multiple aggressive tumor models of melanoma and
  breast cancer when combining ch1N11, the preclinical equivalent to bavituximab, with anti-CTLA-1 and anti-PD-1 agents
  compared to anti-CTLA-1 and anti-PD-1 agents alone. These data further support the combination of bavituximab and
  other immune checkpoint inhibitors.
- Clinical translational data from six patients from the company's Immuno-Oncology Development Program in conjunction
  with the Phase II IST that evaluated bavituximab in combination with sorafenib in patients with advanced hepatocellular
  carcinoma was presented at the SITC 29th Annual Meeting. These data, to assess and measure changes in immune
  response pre- and post-treatment, show an increase in tumor fighting immune cells (particularly CD8 T cells) following
  one cycle of treatment with bavituximab, further confirming in patients what has been shown for PS-targeting antibodies
  in multiple preclinical cancer models.
- Preclinical data from recently conducted studies will be presented in a poster titled: "Antibody-mediated Blockade of Phosphatidylserine Enhances the Anti-tumor Activity of Immune Checkpoint Inhibitor α-PD-1 by Affecting Myeloid Derived Suppressor Cells (MDSC) and Lymphocyte Populations in a Breast Tumor Microenvironment" at the 2014 San Antonio Breast Cancer Symposium on December 12, 2014 in San Antonio, Texas.

The company is also exploring other applications for the PS-targeting platform outside of cancer therapy. These efforts include:

### 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.

### ANTI-VIRAL PROGRAM

The company announced the publication of a manuscript in the Vaccines and Therapies for Biodefense Agents special edition of the peer-reviewed *Journal of Immunology Research*. The paper discusses preclinical research demonstrating that the company's lead drug candidate bavituximab exhibits specific and strong binding to Ebola virions and Ebola virus-infected cells in vitro. These data warrant further collaborative investigation in Ebola and other infectious diseases including combinations with vaccines and active therapies that have shown promise.

### **AVID BIOSERVICES**

Avid Bioservices, Inc. is the contract manufacturing subsidiary of Peregrine. Avid provides high quality clinical and commercial manufacturing services under cGMP for the biotechnology and biopharmaceutical industries.

In a press release issued this morning, the company announced the initiation of an expansion of manufacturing capacity for Avid Bioservices that will help meet the increased demands of this growing business while creating sufficient capacity for the

commercial manufacturing of bavituximab. This facility will employ an innovative and flexible modular clean room design and the latest single-use technologies that provide expanded capacity to meet the growing needs of Avid's existing and future clients. The capacity expansion will take place within an existing 40,000 square foot warehouse located adjacent to the company's current campus. The new cGMP facility will accommodate multiple single-use bioreactors of up to 2,000 liters, downstream processing suites, and dedicated support utilities that will allow for the production of a variety of biological products.

"The success of our contract manufacturing business has led us to evaluate strategic options to expand our manufacturing capacity that will support the future growth of our manufacturing business as well as the anticipated commercial launch of bavituximab," said Paul Lytle, chief financial officer of Peregrine. "This facility will allow us to achieve both of these stated goals in the most efficient and cost effective manner."

## FINANCIAL RESULTS

Total revenues for the second quarter of FY 2015 were \$6,300,000, compared to \$7,354,000 for the same quarter of the prior fiscal year. The decrease was primarily attributed to a decrease 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 second quarter FY 2015 were \$6,263,000, compared to \$7,354,000 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 second quarter of FY 2015 were \$18,437,000, compared to \$15,168,000 in the second quarter of FY 2014. This increase was primarily attributable to the current quarter increase in research and development expenses associated with the SUNRISE Phase III trial combined with an incremental increase in selling, general and administrative expenses. For the second quarter FY 2015, research and development expenses were \$10,003,000, compared to \$6,957,000 for the second quarter of FY 2014. For the second quarter of FY 2015, selling, general and administrative expenses were \$4,295,000, compared to \$4,016,000 for the second quarter of FY 2014.

Peregrine's consolidated net loss attributable to common stockholders was \$13,131,000, or \$0.07 per share, for the second quarter of FY 2015, compared to a net loss attributable to common stockholders of \$7,790,000, or \$0.05 per share, for the same quarter of the prior year.

Peregrine reported \$64,439,000 in cash and cash equivalents as of October 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, December 10, 2014, at 4:30 PM EST (1:30 PM PST).

To listen to the conference call, please dial (877) 312-5443 or (253) 237-1126 and request the Peregrine Pharmaceuticals conference call.

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 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. (<a href="https://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="https://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 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 or additional clinical trials, such as a breast cancer trial, 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 data from the company's Immuno-Oncology Development Program and/or translational studies may not correlate to the results of future 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.

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# PEREGRINE PHARMACEUTICALS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

		Three Months Ended October 31,				Six Months Ended October 31,			
		2014		2013		2014		2013	
		Unaudited		Unaudited		Unaudited		Unaudited	
REVENUES:									
Contract manufacturing revenue	\$	6,263,000	\$	7,354,000	\$	11,759,000	\$	11,935,000	
License revenue	_	37,000	_	<u>-</u>	_	37,000	_	107,000	
Total revenues		6,300,000		7,354,000		11,796,000		12,042,000	
COSTS AND EXPENSES:									
Cost of contract manufacturing		4,139,000		4,195,000		7,722,000		6,865,000	
Research and development		10,003,000		6,957,000		20,204,000		12,261,000	
Selling, general and administrative	_	4,295,000	_	4,016,000	_	9,178,000	_	8,350,000	
Total costs and expenses	_	18,437,000	_	15,168,000	_	37,104,000	_	27,476,000	
LOSS FROM OPERATIONS	_	(12,137,000)	_	(7,814,000)	_	(25,308,000)	_	(15,434,000)	
OTHER INCOME (EXPENSE):									
Interest and other income		37,000		24,000		79,000		45,000	
Interest and other expense	_		_	<u>-</u>	_	<u>-</u>	_	(1,000)	
NET LOSS	\$_	(12,100,000)	\$	(7,790,000)	\$_	(25,229,000)	\$	(15,390,000)	
COMPREHENSIVE LOSS	\$_	(12,100,000)	\$	(7,790,000)	\$_	(25,229,000)	\$	(15,390,000)	
Series E preferred stock accumulated dividends	_	(1,031,000)	_		_	(1,802,000)	_		
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$</u> _	(13,131,000)	\$	(7,790,000)	<u>\$</u> _	(27,031,000)	\$_	(15,390,000)	
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:									
Basic and Diluted	_	179,962,275	_	156,948,226	_	179,540,265	_	153,170,928	
BASIC AND DILUTED LOSS PER COMMON SHARE	<u>\$</u> _	(0.07)	\$	(0.05)	<u>\$</u> _	(0.15)	\$_	(0.10)	

PEREGRINE PHARMACEUTICALS, INC.

# **CONDENSED CONSOLIDATED BALANCE SHEETS**

		OCTOBER 31, 2014	APRIL 30, 2014	
		Unaudited		
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	\$	64,439,000	\$	77,490,000
Trade and other receivables, net		3,361,000		1,332,000
Inventories		5,379,000		5,530,000
Prepaid expenses and other current assets, net	_	1,189,000		1,419,000
Total current assets		74,368,000		85,771,000
Property and equipment, net		5,398,000		2,447,000
Other assets		1,671,000		2,327,000
TOTAL ASSETS	\$	81,437,000	\$	90,545,000
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES:				
Accounts payable	\$	3,840,000	\$	2,434,000
Accrued clinical trial and related fees		2,537,000		4,433,000
Accrued payroll and related costs		3,472,000		3,837,000
Deferred revenue, current portion		3,612,000		5,241,000
Customer deposits		7,549,000		5,760,000
Other current liabilities	_	572,000		502,000
Total current liabilities		21,582,000		22,207,000
Deferred revenue, less current portion		-		292,000
Other long-term liabilities		1,078,000		347,000
Commitments and contingencies				
STOCKHOLDERS' EQUITY:				
Preferred stock-\$0.001 par value; authorized 5,000,000 shares; issued and outstanding 1,177,858 and 775,000, respectively		1,000		1,000
Common stock-\$0.001 par value; authorized 325,000,000 shares; outstanding 182,000,583 and 178,871,164, respectively		182,000		179,000
Additional paid-in capital		487,089,000		470,785,000
Accumulated deficit		(428,495,000)		(403,266,000)
Total stockholders' equity	_	58,777,000		67,699,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	81,437,000	\$	90,545,000

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