

# Peregrine Pharmaceuticals Reports Financial Results for First Quarter of Fiscal Year 2016 and Recent Developments

--Peregrine and AstraZeneca to Collaborate on Immuno-Oncology Combination Clinical Trial--

--Phase III SUNRISE Clinical Trial on Track to Complete Patient Enrollment by Calendar Year-End 2015--

--Avid Bioservices Reports \$9.4 Million in First Quarter Revenue--

TUSTIN, Calif., Sept. 09, 2015 (GLOBE NEWSWIRE) -- Peregrine Pharmaceuticals, Inc. (NASDAQ:PPHM) (NASDAQ:PPHMP), a biopharmaceutical company focused on developing therapeutics to stimulate the body's immune system to fight cancer, today announced financial results for the first quarter of fiscal year (FY) 2016 ended July 31, 2015, and provided an update on its advancing clinical pipeline and other corporate developments.

## Highlights Since April 30, 2015:

"Over the years, Peregrine's foundational science and positive clinical results have consistently pointed to bavituximab's potential as a high-value, next-generation anti-cancer agent," said Steven W. King, president and chief executive officer of Peregrine. "In the last three months, these achievements have compelled others to align with us as we continue to develop bavituximab. In May, Peregrine announced an exciting collaboration with Memorial Sloan Kettering Cancer Center to evaluate combinations of bavituximab with other checkpoint inhibitors and immune stimulatory agents for the purpose of developing new and increasingly effective anti-cancer treatments. Only three months later, we announced a collaboration with AstraZeneca to clinically evaluate bavituximab in combination with AstraZeneca's investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736) in multiple solid tumors. These collaborations with world leaders in immuno-oncology speak to the promise of bavituximab and validate our ever-growing enthusiasm for the investigational product. We look forward to advancing both of these programs and completing enrollment of our SUNRISE trial in the next few months."

# **Clinical Development Highlights**

- Peregrine and AstraZeneca entered into a cancer immunotherapy clinical trial collaboration to evaluate bavituximab in combination with AstraZeneca's investigational anti-PD-L1 immune checkpoint inhibitor, durvalumab (MEDI4736). The planned Phase I/Ib trial will evaluate the safety and efficacy of bavituximab in combination with durvalumab in multiple solid tumors. Peregrine is working closely with AstraZeneca to finalize the trial design.
- Phase III SUNRISE clinical trial in non-small cell lung cancer (NSCLC) continues to enroll patients and remains on track to complete patient enrollment by end of calendar year 2015.
- Peregrine announced plans to expand the bavituximab clinical development program to include a Phase II trial to evaluate
  the combination of bavituximab and Opdivo® (nivolumab), an anti-PD-1 antibody, in previously treated, metastatic
  NSCLC. This trial is expected to be initiated by the end of calendar year 2015.
- Peregrine announced plans to expand the bavituximab clinical development program to include a Phase II/III trial to evaluate bavituximab with chemotherapy combinations in HER2-negative metastatic breast cancer. This trial is expected to be initiated by the end of calendar year 2015.

# **Supportive Research Highlights**

- Peregrine and Memorial Sloan Kettering Cancer Center entered into a research agreement to explore the potential of Peregrine's proprietary PS-targeting antibody platform. The goal of the research is to identify effective treatments combining bavituximab with other checkpoint inhibitors or immune stimulating agents.
- New data presented at the International Association for the Study of Lung Cancer's (IASLC's) World Conference on Lung Cancer (WCLC) from a translational study of bavituximab demonstrated the ability of bavituximab, alone or in combination with docetaxel, to induce signs of immune activation in non-small cell lung cancer (NSCLC) patient-derived tumor samples, particularly when there was negative PD-L1 expression in the tumor sample. These data further support the potential

mechanistic synergies for bavituximab with chemotherapy and checkpoint inhibitors targeting the PD-1/PD-L1 pathway.

- Summary data presented at the Combination Immunotherapy Strategies session at the 10<sup>th</sup> Annual Immunotherapy and Vaccine Summit (ImVacS), highlighted key findings from several recent bavituximab-focused studies including: the potential of bavituximab to shift the tumor microenvironment from immuno-suppressive in which tumors evade immune detection to a state of immune activation in which the immune system recognizes and fights the tumor; bavituximab's potential to increase the number of activated CD8+ cells in the tumor, which stimulates PD-1 expression, potentially increasing the number of patients able to respond to PD-1 and PD-L1 targeting immunotherapies; and, results from several clinical and preclinical studies in a range of tumor types showing that bavituximab and bavituximab-like antibodies, in combination with conventional therapy, have consistently demonstrated estimated survival curves that plateau.
- Data from preclinical studies presented at the 2015 ASCO annual meeting demonstrated the ability of the company's PStargeting antibodies to significantly increase the prevalence of tumor infiltrating CD8+ T-cells and immune-activating cytokines, while decreasing tumor-promoting macrophages and myeloid cells. These findings highlight the ability of the antibodies to enhance the anti-tumor effects of both chemotherapy and immune checkpoint inhibitors.

#### **Avid Bioservices Highlights**

- Avid's new manufacturing suite is fully constructed and the first internal pilot run is currently underway to verify all systems and equipment are properly functioning. Company plans to announce the launch of the new facility in the near term, allowing us to meet our internal manufacturing timelines as well as those of our third-party clients.
- Contract manufacturing committed backlog reached \$42 million from existing customers covering services to be completed in FY 2016 and into FY 2017.

## **Corporate Highlights**

• The European Patent Office (EPO) granted Patent Number 2,269,656, licensed to Peregrine titled "Selected Antibodies Binding to Aminophospholipids and their Use in Treatment, Such as Cancer." The patent covers bavituximab as a composition of matter and for use in therapy, such as for treating cancer including in combination with radiotherapy or chemotherapy, e.g., with docetaxel. This important patent expands upon the company's intellectual property portfolio, which now numbers more than 140 worldwide issued patents and pending applications for the bavituximab oncology program.

#### **Financial Results**

Total revenues for the first quarter of FY 2016 were \$9,671,000, compared to \$5,496,000 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 2016 were \$9,379,000, compared to \$5,496,000 for the same quarter of the prior fiscal year. Peregrine expects third-party contract manufacturing revenue for FY 2016 to be between \$30 and \$35 million. In addition to providing biomanufacturing services to its third-party clients, Avid will continue to support the clinical and potential commercialization of bavituximab.

Total costs and expenses in the first quarter of FY 2016 were \$23,425,000, compared to \$18,667,000 in the first quarter of FY 2015. This increase was primarily attributable to current quarter increases in research and development expenses associated with the SUNRISE Phase III trial and increases in the cost of contract manufacturing associated with higher reported revenue. For the first quarter of FY 2016, research and development expenses were \$13,918,000, compared to \$10,201,000 for the first quarter of FY 2015. For the first quarter of FY 2016, cost of contract manufacturing was \$4,608,000, compared to \$3,583,000 for the first quarter of FY 2015.

Peregrine's consolidated net loss attributable to common stockholders was \$15,101,000, or \$0.08 per share, for the first quarter of FY 2016, compared to a net loss attributable to common stockholders of \$14,157,000, or \$0.08 per share, for the same prior year quarter.

Peregrine reported \$59,016,000 in cash and cash equivalents as of July 31, 2015 compared to \$68,001,000 at fiscal year ended April 30, 2015.

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, 2015, 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. 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 focused on the treatment of cancer. The company's lead immunotherapy candidate, bavituximab, is in Phase III development for the treatment of second-line non-small cell lung cancer (the "SUNRISE trial") along with several investigator-sponsored trials evaluating other treatment combinations and additional oncology indications. 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. For more information, please visit <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 experience delays in the enrollment of patients in the Phase III SUNRISE trial and that the Phase III SUNRISE trial 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 its other contemplated clinical trials, the risk that the company may experience delays in initiating its other contemplated clinical trials, the risk that data from pre-clinical and translational 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, 2015 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.

THREE MONTHS ENDED

#### PEREGRINE PHARMACEUTICALS, INC.

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

	THREE MONTHS ENDED				
	Jı	July 31, 2015		July 31, 2014	
	l	Unaudited		Unaudited	
REVENUES:					
Contract manufacturing revenue	\$	9,379,000	\$	5,496,000	
License revenue		292,000			
Total revenues		9,671,000		5,496,000	
COSTS AND EXPENSES:					
Cost of contract manufacturing		4,608,000		3,583,000	
Research and development		13,918,000		10,201,000	
Selling, general and administrative		4,899,000		4,883,000	
Total costs and expenses		23,425,000		18,667,000	
LOSS FROM OPERATIONS		(13,754,000)	(	(13,171,000)	

Interest and other income	31,000	42,000
NET LOSS	\$ (13,723,000)	\$ (13,129,000)
COMPREHENSIVE LOSS	\$ (13,723,000)	\$ (13,129,000)
Series E preferred stock accumulated dividends	(1,378,000)	(1,028,000)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ (15,101,000)	\$ (14,157,000)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING Basic and diluted	197,317,374	179,118,255
BASIC AND DILUTED LOSS PER COMMON SHARE	\$ (0.08)	\$ (0.08)

## PEREGRINE PHARMACEUTICALS, INC.

# CONDENSED CONSOLIDATED BALANCE SHEETS

	JULY 31, 2015	APRIL 30, 2015	
400570	Unaudited		
ASSETS CURRENT ACCETS.			
CURRENT ASSETS:	\$ 59,016,000	\$ 68,001,000	
Cash and cash equivalents Trade and other receivables, net	1,805,000	3,813,000	
Inventories	10,457,000	7,354,000	
Prepaid expenses and other current assets, net	1,052,000	1,355,000	
Total current assets	72,330,000		
	18,395,000	80,523,000 15,124,000	
Property and equipment, net Other assets	1,307,000	1,817,000	
	\$ 92,032,000		
TOTAL ASSETS	\$ 92,032,000	\$ 97,464,000	
LIADII ITIES AND STOCKHOLDEDS EQUITY			
LIABILITIES AND STOCKHOLDERS' EQUITY  CURRENT LIABILITIES:			
Accounts payable	\$ 9,840,000	\$ 10,385,000	
Accrued clinical trial and related fees	4,106,000	3,910,000	
Accrued payroll and related costs	3,094,000	4,606,000	
Deferred revenue	8,291,000	6,630,000	
Customer deposits	9,599,000	11,363,000	
Other current liabilities	620,000	437,000	
Total current liabilities	35,550,000	37,331,000	
Total current habilities	33,330,000	37,331,000	
Deferred rent, less current portion	1,036,000	1,098,000	
Commitments and contingencies	1,000,000	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
STOCKHOLDERS' EQUITY:			
Preferred stock - \$0.001 par value; authorized 5,000,000 shares; issued and outstanding - 1,574,764 and	2,000	2,000	
1,574,764, respectively			
Common stock-\$0.001 par value; authorized 325,000,000 shares; issued and outstanding - 200,983,948 and	201,000	193,000	
193,346,627, respectively			
Additional paid-in capital	522,590,000	512,464,000	
Accumulated deficit	(467,347,000)	(453,624,000)	
Total stockholders' equity	55,446,000	59,035,000	
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 92,032,000	\$ 97,464,000	

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