

# PEREGRINE PHARMACEUTICALS INC

## **FORM 8-K** (Current report filing)

Filed 12/12/16 for the Period Ending 12/12/16

Address	14282 FRANKLIN AVE TUSTIN, CA 92780
Telephone	7145086000
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Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	04/30

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, DC 20549

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **December 12, 2016**

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**PEREGRINE PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State of other jurisdiction  
of incorporation)

**001-32839**  
(Commission File Number)

**95-3698422**  
(IRS Employer  
Identification No.)

**14282 Franklin Avenue, Tustin, California 92780**  
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: **(714) 508-6000**

**Not Applicable**  
(Former name or former address, if changed since last report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2 below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).
  - Soliciting material pursuant to Rule 14A-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION**

On December 12, 2016, Peregrine Pharmaceuticals, Inc. (the “Company”) issued a press release to report the Company’s financial results for the second quarter ended October 31, 2016. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1. No additional information is included in this Current Report on Form 8-K.

The information included in this Current Report on Form 8-K, including the exhibit hereto, shall not be deemed “filed” for purposes of, nor shall it be deemed incorporated by reference in, any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as expressly set forth by specific reference in such a filing.

**ITEM 7.01 REGULATION FD DISCLOSURE**

On December 12, 2016, at 4:30 p.m. ET/1:30 p.m. PT, the Company will host a conference call to discuss its second quarter ended October 31, 2016 financial results. The webcast of the conference call will be archived on the Company’s website for approximately 30 days.

**ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS**

(d) Exhibits. The following material is filed as an exhibit to this Current Report on Form 8-K:

**Exhibit  
Number**

99.1 Press Release issued December 12, 2016

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PEREGRINE PHARMACEUTICALS, INC.

Date: December 12, 2016

By: /s/ Paul J. Lytle  
Paul J. Lytle  
Chief Financial Officer

**EXHIBIT INDEX**

<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
99.1	Press Release issued December 12, 2016



## Contacts:

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## **Peregrine Pharmaceuticals Reports Financial Results for Second Quarter of Fiscal Year 2017 and Recent Developments**

*-- Avid Posts Record Revenue of \$23.4 Million During Second Quarter FY 2017 with Contracted Backlog of Future Business Currently at \$73 Million --*

*-- Beta-2 Glycoprotein-1 ( $\beta$ 2GPI) Identified as a Biomarker that Correlates with Statistically Significant Improvement in Overall Survival for Patients Receiving the Baviximab Combination Compared to Chemotherapy Alone from the Phase III SUNRISE Trial --*

*-- Multiple Preclinical Presentations Collectively Point to Baviximab's Ability to Enhance the Efficacy of Checkpoint Inhibitors by Triggering Immune Active Tumor Environment --*

**TUSTIN, Calif.**, December 12, 2016 -- Peregrine Pharmaceuticals, Inc. (NASDAQ:PPHM) (NASDAQ:PPHMP), a biopharmaceutical company committed to improving patient lives by manufacturing high quality products for biotechnology and pharmaceutical companies and advancing its proprietary R&D pipeline, today announced financial results for the second quarter of fiscal year (FY) 2017 ended October 31, 2016, and provided an update on its contract manufacturing business, clinical pipeline and other corporate developments.

### **Highlights Since July 31, 2016**

"The Avid business is on track to continue its revenue growth this fiscal year as we move toward overall profitability within the next 18 months. Our two facilities have the potential to generate in excess of \$80 million in revenue, leaving additional capacity for revenue growth beyond fiscal year 2017 revenue guidance," stated Steven W. King, president and chief executive officer of Peregrine. "We are moving forward with our plans to construct a third manufacturing facility, with an eye toward efficiencies that will reduce the overall cost of construction and operation. While this may delay the new facility launch until later in calendar year 2017, we currently have adequate existing capacity to continue meeting the needs of our current clients while also bringing in new customers so we do not expect it to impact our near-term ability to grow top-line revenue as originally planned. Independently, Avid is a successful and growing CDMO business generating significant revenue and one of our key goals going forward is to help ensure that its value is appropriately represented in the market cap of our overall business."

Mr. King continued, "During, and subsequent to, the second quarter, we announced a series of important findings, all of which will contribute to our future development of baviximab. Our ongoing analysis of the Phase III SUNRISE data has revealed a promising biomarker that may give us insight into key patient populations. We are actively evaluating additional potential biomarkers and we hope to identify a profile for patients who will receive therapeutic benefit from treatment with baviximab. Concurrent with our internal clinical work, our collaborators at NCCN are in the process of initiating trials for three new baviximab combination treatments, which we expect to begin enrolling patients in the coming months. What is exciting is that the NCCN studies will help build on developments we are seeing from our internal scientists, as well as our collaborators at Duke, Rutgers and Memorial Sloan Kettering Cancer Center. Together, we presented compelling data supporting our long-standing belief that baviximab significantly impacts the tumor microenvironment, creating a more immune active environment in which other therapies, including checkpoint inhibitors, are able to have a greater anti-tumor effect. These findings are highly validating and we look forward to continuing our work with these world-class institutions to help guide clinical development."

### **Avid Bioservices Highlights**

"Growing top-line revenue is a key focus and we are pleased to report a 53% improvement in contract manufacturing revenue for the current six-month period compared to the same period last fiscal year. In addition, our revenue guidance for the second quarter was targeted to exceed \$20 million and we achieved \$23.4 million in contract manufacturing revenue as we worked closely with the third-party testing laboratory to resolve the unexpected delays in testing we encountered during the first quarter. As a result, we reaffirm our manufacturing revenue guidance of between \$50 and \$55 million for the full fiscal year," stated Paul Lytle, chief financial officer of Peregrine. "We also continued to advance the validation of three separate manufacturing processes related to third-party customer products that could lead to future commercial manufacturing for these products. While these activities generally have a higher cost of manufacturing, which impacted our gross margin during the second quarter, we believe our investment in these products will provide us future revenue opportunities once these products are approved."

- The company reaffirms its manufacturing revenue guidance for the full FY 2017 of \$50 - \$55 million.
- Avid's current manufacturing revenue backlog is \$73 million, representing estimated future manufacturing revenue to be recognized under committed contracts. This backlog mostly covers revenue to be recognized during the remainder of fiscal year 2017 and fiscal year 2018.

### **Clinical Development Highlights**

- Through the ongoing analysis of the Phase III SUNRISE data, Peregrine scientists identified a correlation between overall survival and pre-treatment levels of the biomarker, beta-2 glycoprotein-1 ( $\beta$ 2GP1), which we presented at ESMO in October.
  - o Data demonstrated that patients with pre-treatment  $\beta$ 2GP1 levels between 200 and 240  $\mu$ g/mL - representing approximately 30% of randomized patients - achieved a statistically significant, 5.5-month improvement, from 7.7 months to 13.2 months, in median overall survival as compared to patients in the control group with the same range of  $\beta$ 2GP1 levels.
- Peregrine's research collaboration with NCCN is advancing as planned, with grants awarded to three investigators to support research of bavituximab in combination with other therapeutics for the following studies:
  - o Phase I Trial of Sorafenib and Bavituximab Plus Stereotactic Body Radiation Therapy (SBRT) for Unresectable Hepatitis C Associated Hepatocellular Carcinoma
  - o Phase I/II Clinical Trial of Bavituximab with Radiation and Temozolomide for Patients with Newly Diagnosed Glioblastoma
  - o Phase II Study of Pembrolizumab and Bavituximab for Progressive Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck

The company expects these trials to begin over the coming months.

## Research Highlights

- Peregrine scientists and collaborators from Duke University Medical Center, Rutgers University College of Medicine, and Memorial Sloan Kettering Cancer Center each presented compelling data demonstrating that shifts in the tumor microenvironment from immune suppressed to immune active occurred when a baviximab equivalent antibody was administered as part of a combination treatment regimen. Presentations addressed multiple phosphatidylserine (PS)-targeting combinations, including those with checkpoint inhibitors such as anti-PD-1, anti-PD-L1 and anti-LAG3, as well as with radiation or chemotherapy. These data suggest that the addition of PS-targeting reverses an immunosuppressive tumor environment, creating an immune active tumor microenvironment that can potentially convert patients that generally do not respond to immuno-oncology (I-O) therapies into responders. Key presentations were made at the Second International Cancer Immunotherapy Conference in September, the American Association for Cancer Research's Tumor Immunology and Immunotherapy Conference in October, the Society for Immunotherapy of Cancer (SITC) in November, and the San Antonio Breast Cancer Symposium in December.

## Financial Highlights and Results

- Peregrine continues to execute its previously-announced strategy to reach sustained profitability by increasing contract manufacturing revenue while decreasing research and development expenses, with the goal of reaching profitability 18 months from now. During the first six months of FY 2017, the company made significant progress toward this goal with contract manufacturing revenues increasing 53% compared to the first six months of FY 2016 and research and development expenses decreasing by 45% compared to the first six months of FY 2016.
  - Contract manufacturing revenue from Avid's clinical and commercial biomanufacturing services provided to its third-party customers increased to \$23,370,000 for the second quarter of FY 2017 compared to \$9,523,000 for the second quarter of FY 2016. In addition, as previously-announced, a backlog at a third-party testing lab, unrelated to product quality, required that the recognition of some revenue be shifted from the first quarter to the second quarter of fiscal year 2017.
  - Total costs and expenses for the second quarter of FY 2017 were \$27,447,000, compared to \$23,347,000 for the second quarter of FY 2016. For the second quarter of FY 2017, research and development expenses decreased 51% to \$7,022,000, compared to \$14,190,000 for the second quarter of FY 2016. Cost of contract manufacturing increased to \$15,441,000 in the second quarter of FY 2017 compared to \$4,741,000 for the second quarter of FY 2016, primarily due to an increase in the cost of contract manufacturing associated with higher reported revenue. Also contributing to this increase and impacting gross margins for the period is the higher cost of operating the new Myford facility as well as the higher cost associated with performing process validation runs during the quarter. For the second quarter of FY 2017, selling, general and administrative expenses increased to \$4,984,000 compared to \$4,416,000 for the second quarter of FY 2016 primarily due to the company's growing manufacturing business.
  - Peregrine's consolidated net loss attributable to common stockholders was \$5,498,000 or \$0.02 per share, for the second quarter of FY 2017, compared to a net loss attributable to common stockholders of \$14,578,000, or \$0.07 per share, for the same prior year quarter.
  - Peregrine reported \$49,055,000 in cash and cash equivalents as of October 31, 2016, compared to \$61,412,000 at fiscal year ended April 30, 2016.

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 12, 2016, at 4:30 PM ET (1:30 PM PT).

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: <http://ir.peregrineinc.com/events.cfm>.

## About Peregrine Pharmaceuticals, Inc.

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company committed to improving the lives of patients by delivering high quality pharmaceutical products through its contract development and manufacturing organization (CDMO) services and through advancing and licensing its investigational immunotherapy and related products. Peregrine's in-house CDMO services, including cGMP manufacturing and development capabilities, are provided through its wholly-owned subsidiary Avid Bioservices, Inc. ([www.avidbio.com](http://www.avidbio.com)), which provides development and biomanufacturing services for both Peregrine and third-party customers. The company is also working to evaluate its lead immunotherapy candidate, bavituximab, in combination with immune stimulating therapies for the treatment of various cancers, and developing its proprietary exosome technology for the detection and monitoring of cancer. For more information, please visit [www.peregrineinc.com](http://www.peregrineinc.com).

## About Avid Bioservices

Avid Bioservices provides a comprehensive range of process development, high quality cGMP clinical and commercial manufacturing services for the biotechnology and biopharmaceutical industries. With over 15 years of experience producing monoclonal antibodies and recombinant proteins in batch, fed-batch and perfusion modes, Avid's services include cGMP clinical and commercial product manufacturing, purification, bulk packaging, stability testing and regulatory strategy, submission and support. The company also provides a variety of process development activities, including cell line development and optimization, cell culture and feed optimization, analytical methods development and product characterization. For more information about Avid, please visit [www.avidbio.com](http://www.avidbio.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 forward-looking statements involve risks and uncertainties including, but not limited to, the risk that the biomarker data does not support the development of a specific profile for patients who will receive therapeutic benefit from treatment with bavituximab, the risk that one or more of the NCCN grant funded investigator-initiated clinical studies may experience initiation and/or enrollment delays, the risk that data from one or more of the NCCN grant funded investigator-initiated clinical studies does not support further evaluation, the risk that the results from the pre-clinical studies is not replicated in human clinical trials, the risk that the company may not have or raise adequate financial resources from debt and/or equity financings and/or Avid's manufacturing operations to fund the further development of bavituximab, the risk that Avid's revenue growth may slow or decline, the risk that the company does not achieve profitability in 18 months, the risk that Avid may experience technical difficulties in processing customer orders, including delays in third party release testing, which could delay delivery of products to customers, revenue recognition and receipt of payment, the risk that one or more existing Avid customers terminates its contract prior to completion or reduces its demand for manufacturing services, and the risk that the new clinical manufacturing facility will not be operational in by the end of, or begin generating revenue in, 2017, due to construction or other delays or causes. 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, 2016 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.*

PEREGRINE PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

	THREE MONTHS ENDED OCTOBER 31,		SIX MONTHS ENDED OCTOBER 31,	
	2016	2015	2016	2015
<b>REVENUES:</b>				
Contract manufacturing revenue	\$ 23,370,000	\$ 9,523,000	\$ 28,979,000	\$ 18,902,000
License revenue	—	—	—	292,000
Total revenues	<u>23,370,000</u>	<u>9,523,000</u>	<u>28,979,000</u>	<u>19,194,000</u>
<b>COSTS AND EXPENSES:</b>				
Cost of contract manufacturing	15,441,000	4,741,000	18,503,000	9,349,000
Research and development	7,022,000	14,190,000	15,591,000	28,108,000
Selling, general and administrative	4,984,000	4,416,000	10,044,000	9,315,000
Total costs and expenses	<u>27,447,000</u>	<u>23,347,000</u>	<u>44,138,000</u>	<u>46,772,000</u>
<b>LOSS FROM OPERATIONS</b>	<u>(4,077,000)</u>	<u>(13,824,000)</u>	<u>(15,159,000)</u>	<u>(27,578,000)</u>
Interest and other income	21,000	626,000	46,000	657,000
<b>NET LOSS</b>	<u>\$ (4,056,000)</u>	<u>\$ (13,198,000)</u>	<u>\$ (15,113,000)</u>	<u>\$ (26,921,000)</u>
<b>COMPREHENSIVE LOSS</b>	<u>\$ (4,056,000)</u>	<u>\$ (13,198,000)</u>	<u>\$ (15,113,000)</u>	<u>\$ (26,921,000)</u>
Series E preferred stock accumulated dividends	(1,442,000)	(1,380,000)	(2,477,000)	(2,413,000)
<b>NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS</b>	<u>\$ (5,498,000)</u>	<u>\$ (14,578,000)</u>	<u>\$ (17,590,000)</u>	<u>\$ (29,334,000)</u>
<b>WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:</b>				
Basic and Diluted	<u>244,815,767</u>	<u>203,942,411</u>	<u>242,205,428</u>	<u>200,629,892</u>
<b>BASIC AND DILUTED LOSS PER COMMON SHARE</b>	<u>\$ (0.02)</u>	<u>\$ (0.07)</u>	<u>\$ (0.07)</u>	<u>\$ (0.15)</u>

## PEREGRINE PHARMACEUTICALS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

	OCTOBER 31, 2016	APRIL 30, 2016
	<i>Unaudited</i>	
<b>ASSETS</b>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 49,055,000	\$ 61,412,000
Trade and other receivables	6,066,000	2,859,000
Inventories	25,924,000	16,186,000
Prepaid expenses and other current assets	1,711,000	1,351,000
Total current assets	<u>82,756,000</u>	<u>81,808,000</u>
Property and equipment, net	23,957,000	24,302,000
Restricted cash	600,000	600,000
Other assets	2,624,000	2,333,000
<b>TOTAL ASSETS</b>	<u>\$ 109,937,000</u>	<u>\$ 109,043,000</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
CURRENT LIABILITIES:		
Accounts payable	\$ 11,572,000	\$ 8,429,000
Accrued clinical trial and related fees	3,639,000	7,594,000
Accrued payroll and related costs	5,280,000	5,821,000
Deferred revenue	17,980,000	10,030,000
Customer deposits	26,928,000	24,212,000
Other current liabilities	1,012,000	1,488,000
Total current liabilities	<u>66,411,000</u>	<u>57,574,000</u>
Deferred rent, less current portion	1,347,000	1,395,000
Commitments and contingencies		
STOCKHOLDERS' EQUITY:		
Preferred stock - \$0.001 par value; authorized 5,000,000 shares; 1,647,760 and 1,577,440 issued and outstanding at October 31, 2016 and April 30, 2016, respectively	2,000	2,000
Common stock-\$0.001 par value; authorized 500,000,000 shares; 251,765,279 and 236,930,485 issued and outstanding at October 31, 2016 and April 30, 2016, respectively	252,000	237,000
Additional paid-in capital	566,314,000	559,111,000
Accumulated deficit	(524,389,000)	(509,276,000)
Total stockholders' equity	<u>42,179,000</u>	<u>50,074,000</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u>\$ 109,937,000</u>	<u>\$ 109,043,000</u>

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