

PEREGRINE PHARMACEUTICALS INC

FORM 8-K (Current report filing)

Filed 03/13/17 for the Period Ending 03/13/17

Address	14282 FRANKLIN AVE TUSTIN, CA 92780
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Industry	Pharmaceuticals
Sector	Healthcare
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, DC 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (Date of earliest event reported): **March 13, 2017**

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)

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 March 13, 2017, Peregrine Pharmaceuticals, Inc. (the “Company”) issued a press release to report the Company’s financial results for the third quarter ended January 31, 2017. 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 March 13, 2017, at 4:30 p.m. EDT/1:30 p.m. PDT, the Company will host a conference call to discuss its third quarter ended January 31, 2017 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 March 13, 2017

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: March 13, 2017

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

EXHIBIT INDEX

**Exhibit
Number**

Description

99.1

Press Release issued March 13, 2017



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Peregrine Pharmaceuticals Reports Financial Results for the Third Quarter of Fiscal Year 2017 and Recent Developments

-- Avid Revenue Guidance Increased to \$60 - \$65 Million for Full FY 2017 and Contracted Backlog of Future Business Currently at \$70 Million --

-- Multiple Preclinical Studies Demonstrating Baviximab's Ability to Enhance Activity of Immune Stimulating Therapies Accepted for Presentation at AACR --

TUSTIN, Calif., March 13, 2017 -- 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 third quarter of fiscal year (FY) 2017 ended January 31, 2017, and provided an update on its contract manufacturing business, preclinical and clinical pipeline, and other corporate developments.

Highlights Since October 31, 2016

"During the third quarter, Avid's revenue growth continued, which is a strong indicator of the increasing value of this contract development and manufacturing organization (CDMO) business. The steady growth of this business over the past 5 years has been remarkable and we are pleased to see the trend continuing as we move through a number of process validations for clients, which we expect to spur further growth in the future as some or all of those products move to commercialization. We see Avid as a tremendously important asset with solid upside potential that is often overlooked as a value driver for the overall organization. With projected revenue of over \$60 million for the current fiscal year, this is already a strong business in an industry that is expecting substantial growth over the next decade and we are excited about the future of the company," stated Steven W. King, president and chief executive officer of Peregrine, and president of Avid Bioservices. "An important component of our Avid growth strategy is capacity expansion within our Myford facility. We are currently on track to install two 2,000-liter bioreactors in the facility within the next few months with a book of business for the reactors already in place. We believe the total capacity potential of the facility, when operating in campaign mode, can exceed more than \$75 million annually bringing us to well over \$100 million in total potential revenue between our two manufacturing facilities, and giving us adequate capacity to continue Avid revenue growth through FY 2018.

“As we look to the future, based on current operations and projected demand from our existing clients, we have also recently secured additional space within the same building as our Myford facility for which we already have use as part of our existing operations but would also allow us to further expand capacity based on committed business. While we will only begin converting the space into manufacturing capacity once client commitments and other necessary financing is in place, this puts us in an excellent position for continuing to grow the business beyond the coming fiscal year.”

Mr. King continued, "During the quarter, we also achieved a number of goals on the development front. These efforts are highlighted by the three clinical trials under our collaboration with the National Comprehensive Cancer Network (NCCN) which are advancing as planned, and we expect at least two of the trials to be initiated by mid-year. Additionally, we and our collaborators will be presenting a number of studies at the upcoming AACR annual meeting including data from researchers at Memorial Sloan Kettering that support the ability of PS-targeting agents, including bavituximab, to significantly impact the tumor microenvironment, creating a more favorable environment for checkpoint inhibitors. Additionally, our collaborators at the University of Texas Southwestern Medical Center published positive proof-of-concept data for our recently-licensed exosome-based cancer detection platform, which could have broad potential for patients with cancer. Even though we have reduced our R&D expenditures, we are pleased that collaborations such as these are allowing us to continue the advancement of our therapeutic and diagnostic programs as we continue to evaluate the best ways for moving our bavituximab and other PS-targeting programs forward. The combined efforts of growing the Avid biomanufacturing business and these important collaborations are allowing us to make great strides on all fronts."

Avid Bioservices Highlights

"The Avid business continues to build momentum. During the third quarter of FY 2017, contract manufacturing revenue increased 61% to \$10.7 million compared to the third quarter of FY 2016. Given this performance, and our expected fourth quarter results, we are increasing our full FY 2017 revenue guidance from \$50 to \$55 million, to \$60 to \$65 million," stated Paul Lytle, chief financial officer of Peregrine. "We are also pleased to report that we recently leased 42,000 square feet within the same building as our Myford facility, allowing us to leverage existing oversized utilities and infrastructure that should allow us greater operational efficiency and overall cost savings. While we design the new facility within this new space, it's important to note that our two existing commercial facilities have sufficient capacity to continue to grow our contract manufacturing revenue in FY 2018."

- The company is increasing its manufacturing revenue guidance for the full FY 2017 from \$50 - \$55 million, to \$60 - \$65 million.
- Avid's current manufacturing revenue backlog is \$70 million, representing estimated future manufacturing revenue to be recognized under committed contracts. This backlog primarily covers revenue to be recognized during the remainder of fiscal year 2017 and fiscal year 2018.

Clinical Development Highlights

- The three clinical trials under the collaboration with the NCCN are advancing as planned.
 - o Moffitt Cancer Center—A Phase I Trial of Sorafenib and Bavituximab Plus Stereotactic Body Radiation Therapy for Unresectable Hepatitis C Associated Hepatocellular Carcinoma. This protocol is approved and patient screening is expected soon.

Massachusetts General Hospital Cancer Center—Phase I/II Clinical Trial of Bavituximab with Radiation and Temozolomide for Patients with Newly Diagnosed Glioblastoma. This trial is on track to be initiated by mid-calendar 2017.

- o The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins—Phase II Study of Pembrolizumab and Bavituximab for Progressive Recurrent/Metastatic Squamous Cell Carcinoma of the Head and Neck. This trial is on track to be initiated by mid-calendar 2017.
- The company is continuing its comprehensive biomarker analysis of data collected in the Phase III SUNRISE trial.
 - o Through this analysis, and as reported previously, Peregrine scientists have identified a correlation between overall survival and pre-treatment levels of the biomarker, beta-2 glycoprotein-1 (β2GP1).
 - o The results of an analysis of pre-treatment interferon gamma (IFN-γ) will be the subject of a presentation at AACR entitled:

IFN-γ Analysis in Blood and Tissue as a Potential Prognostic and/or Predictive Biomarker

Research Highlights

- Peregrine scientists and collaborators from Memorial Sloan Kettering Cancer Center will present preclinical results from multiple studies at the upcoming AACR meeting in April. Each study evaluates the use of a bavituximab equivalent in combination with immune stimulating therapies. The following abstracts will be presented:
 - o **Memorial Sloan Kettering:** Targeting Phosphatidylserine in Combination with Adoptive T Cell Transfer Eliminates Advanced Tumors without Off-Target Toxicities in a Melanoma Preclinical Model
 - o **Memorial Sloan Kettering (initial findings presented at SITC):** Phosphatidylserine Targeting Antibody in Combination with Tumor Radiation and Immune Checkpoint Blockade Promotes Anti-Tumor Activity in Mouse B16 Melanoma
 - o **Peregrine (initial findings presented at the 2016 Society for Immunotherapy of Cancer Meeting):** Combinational Activity of LAG3 and PD-1 Targeted Therapies is Significantly Enhanced by the Addition of Phosphatidylserine Targeting Antibodies and Establishes an Anti-Tumor Memory Response in Murine Triple Negative Breast Cancer
- Collaborators from the University of Texas Southwestern Medical Center at Dallas, recently published positive proof-of-concept findings for Peregrine’s recently licensed exosome-based cancer detection platform in the peer-reviewed journal, *Oncotarget* . Results demonstrated that those patients with malignant ovarian cancer displayed significantly higher blood PS exosome levels than those with benign tumors, and the malignant and benign groups displayed significantly higher blood PS exosome levels than the healthy subjects.

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 15 months from now. During the first nine months of FY 2017, the company made significant progress toward this goal with contract manufacturing revenues increasing 55% compared to the first nine months of FY 2016 and research and development expenses decreasing by 50% compared to the first nine months of FY 2016.
 - o Contract manufacturing revenue from Avid's biomanufacturing services provided to its third-party customers increased to \$10,747,000 for the third quarter of FY 2017 compared to \$6,672,000 for the third quarter of FY 2016.
 - o Total costs and expenses for the third quarter of FY 2017 were \$18,544,000, compared to \$23,576,000 for the third quarter of FY 2016. For the third quarter of FY 2017, research and development expenses decreased 60% to \$5,989,000, compared to \$15,156,000 for the third quarter of FY 2016. Cost of contract manufacturing increased to \$7,974,000 in the third quarter of FY 2017 compared to \$3,896,000 for the third 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 third quarter of FY 2017, selling, general and administrative expenses increased slightly to \$4,581,000 compared to \$4,524,000 for the third quarter of FY 2016 primarily due to the company's growing manufacturing business.
 - o Peregrine's consolidated net loss attributable to common stockholders was \$9,216,000 or \$0.04 per share, for the third quarter of FY 2017, compared to a net loss attributable to common stockholders of \$18,227,000, or \$0.08 per share, for the same prior year quarter.
 - o Peregrine reported \$41,528,000 in cash and cash equivalents as of January 31, 2017, 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, March 13, 2017, 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: <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), 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.

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.

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 are 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 15 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 manufacturing facility will not be operational in 2019, due to construction or other delays or causes, including the inability to raise the capital to construct the facility. 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 JANUARY 31,		NINE MONTHS ENDED JANUARY 31,	
	2017	2016	2017	2016
REVENUES:				
Contract manufacturing revenue	\$ 10,747,000	\$ 6,672,000	\$ 39,726,000	\$ 25,574,000
License revenue	—	37,000	—	329,000
Total revenues	10,747,000	6,709,000	39,726,000	25,903,000
COSTS AND EXPENSES:				
Cost of contract manufacturing	7,974,000	3,896,000	26,477,000	13,245,000
Research and development	5,989,000	15,156,000	21,580,000	43,264,000
Selling, general and administrative	4,581,000	4,524,000	14,625,000	13,839,000
Total costs and expenses	18,544,000	23,576,000	62,682,000	70,348,000
LOSS FROM OPERATIONS	(7,797,000)	(16,867,000)	(22,956,000)	(44,445,000)
OTHER INCOME (EXPENSE):				
Interest and other income	25,000	34,000	71,000	691,000
Interest and other expense	(2,000)	(14,000)	(2,000)	(14,000)
Total other income, net	23,000	20,000	69,000	677,000
NET LOSS	\$ (7,774,000)	\$ (16,847,000)	\$ (22,887,000)	\$ (43,768,000)
COMPREHENSIVE LOSS	\$ (7,774,000)	\$ (16,847,000)	\$ (22,887,000)	\$ (43,768,000)
Series E preferred stock accumulated dividends	(1,442,000)	(1,380,000)	(3,558,000)	(3,448,000)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ (9,216,000)	\$ (18,227,000)	\$ (26,445,000)	\$ (47,216,000)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic and Diluted	260,811,553	227,389,225	248,407,470	209,549,670
BASIC AND DILUTED LOSS PER COMMON SHARE	\$ (0.04)	\$ (0.08)	\$ (0.11)	\$ (0.23)

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PEREGRINE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS

	JANUARY 31, 2017	APRIL 30, 2016
	<i>Unaudited</i>	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 41,528,000	\$ 61,412,000
Trade and other receivables	5,883,000	2,859,000
Inventories	33,829,000	16,186,000
Prepaid expenses and other current assets	1,747,000	1,351,000
Total current assets	82,987,000	81,808,000
Property and equipment, net	24,143,000	24,302,000
Restricted cash	600,000	600,000
Other assets	3,587,000	2,333,000
TOTAL ASSETS	\$ 111,317,000	\$ 109,043,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 7,696,000	\$ 8,429,000
Accrued clinical trial and related fees	3,127,000	7,594,000
Accrued payroll and related costs	5,637,000	5,821,000
Deferred revenue	26,367,000	10,030,000
Customer deposits	26,210,000	24,212,000
Other current liabilities	941,000	1,488,000
Total current liabilities	69,978,000	57,574,000
Deferred rent, less current portion	1,325,000	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 January 31, 2017 and April 30, 2016, respectively	2,000	2,000
Common stock—\$0.001 par value; authorized 500,000,000 shares; 271,068,464 and 236,930,485 issued and outstanding at January 31, 2017 and April 30, 2016, respectively	271,000	237,000
Additional paid-in capital	571,904,000	559,111,000
Accumulated deficit	(532,163,000)	(509,276,000)
Total stockholders' equity	40,014,000	50,074,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 111,317,000	\$ 109,043,000

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