

PEREGRINE PHARMACEUTICALS INC

FORM 8-K (Current report filing)

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Address	14282 FRANKLIN AVE TUSTIN, CA 92780
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Industry	Biotechnology & Drugs
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): **September 8, 2016**

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 September 8, 2016, Peregrine Pharmaceuticals, Inc. (the “Company”) issued a press release to report the Company’s financial results for the first quarter ended July 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 September 8, 2016, at 4:30 p.m. EDT/1:30 p.m. PDT, the Company will host a conference call to discuss its first quarter ended July 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 September 8, 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: September 8, 2016

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

EXHIBIT INDEX

**Exhibit
Number**

Description _____

99.1

Press Release issued September 8, 2016



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

--SUNRISE Top-line Data Accepted for Late-Breaking Oral Presentation at European Society of Medical Oncology Congress in October 2016 --

-- Avid First Quarter Revenue of \$5.6 Million with Over \$20 Million in Revenue Projected in Second Quarter --

-- Company Reaffirms Revenue Projection of \$50 - \$55 Million for Full FY 2017 with Growing Backlog of Business Currently at \$71 Million --

TUSTIN, Calif., September 8, 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 first quarter of fiscal year (FY) 2017 ended July 31, 2016, and provided an update on its contract manufacturing business, clinical pipeline and other corporate developments.

Highlights Since April 30, 2016

"Since the start of our first quarter, we have steadily executed on our R&D and contract manufacturing objectives. On the R&D front, we recently achieved two important milestones beginning with the recent announcement that the National Comprehensive Cancer Network (NCCN) has awarded grants to three investigators to support bavituximab clinical research. In addition, we are pleased to announce today, that top-line data from our Phase III SUNRISE trial have been accepted for a late-breaking oral presentation at the upcoming meeting of the European Society of Medical Oncology (ESMO) Congress to be held in Copenhagen in early October," stated Steven W. King, president and chief executive officer of Peregrine. "The presentation at ESMO will be a great opportunity to share clinical data from the trial in conjunction with initial results from our ongoing biomarker analyses which are already highly encouraging. The primary goal of the biomarker analysis is to identify a biomarker pattern for patients that receive the most benefit from a bavituximab-containing therapeutic regimen and we look forward to sharing the results of the ongoing analysis with more data expected later in the year. Our collaboration with the NCCN has been an important part of our plans for advancing the bavituximab clinical program in a cost effective way. The grants that were awarded represent clinical trials with novel bavituximab combinations in glioblastoma, head and neck cancer, and hepatocellular carcinoma including an immunotherapy combination, which is a major focus for advancing the program. Taken together, these developments are setting the stage for new data throughout the rest of 2016 and into 2017."

Mr. King continued, "On the manufacturing front, it remains an extraordinarily busy time. Based on the high demand for services, we remain on track to meet our current fiscal year revenue projections as we look to continue growing the business. Our ultimate goal remains to reach overall profitability within the next 21 months and Avid will be an important driver for achieving that goal in combination with making strategic investments in R&D while pursuing partnerships to help advance our programs."

Avid Bioservices Highlights

"Our biomanufacturing business was extremely busy this past quarter as the team remained on track according to the planned production schedule including initiating several process validation runs and ongoing commercial manufacturing activities. Despite being on track from a production standpoint, first quarter FY 2017 revenues were lower than expected due to a testing backlog at a third-party testing laboratory that delayed the shipment of manufacturing runs. As a result of the backlog being resolved, we expect revenue to exceed \$20 million in the second quarter as we shift revenue recognition from the first quarter to the second quarter of fiscal year 2017. We believe this delay to be an anomaly, and we reaffirm our revenue guidance of between \$50 and \$55 million for the full fiscal year," stated Paul Lytle, chief financial officer of Peregrine.

- The company is projecting manufacturing revenue for the full FY 2017 of \$50 - \$55 million.
- Avid's current manufacturing revenue backlog is \$71 million, representing estimated future manufacturing revenue to be recognized under committed contracts. This backlog covers revenue to be recognized during the remainder of fiscal year 2017 and into fiscal year 2018.
- In response to demand for manufacturing services, the company is designing a third manufacturing facility dedicated to clinical manufacturing that is anticipated to significantly increase Avid's manufacturing capacity. The new clinical suite is expected to be complete and ready for clinical manufacturing activities by mid calendar year 2017.

Clinical Development Highlights

- SUNRISE top-line data, including initial biomarker profile data, have been accepted for oral presentation at the European Society of Medical Oncology (ESMO) Congress in October 2016.
- 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 in early calendar year 2017.

Research Highlights

- Our internal efforts and collaboration with Memorial Sloan Kettering Cancer Center continues to advance. The goal of this pre-clinical work is 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. We expect initial results from our internal work and this collaboration to be presented at multiple conferences during the Fall of 2016.
- Peregrine in-licensed a novel exosome technology from UT Southwestern that has potential for cancer detection and monitoring applications. This technology aligns directly with the company's expertise, its proprietary PS-targeting platform and the bavituximab development program. As such, there are opportunities to use this technology as both a complementary tool in bavituximab's ongoing development, as well as more broadly as the basis for novel cancer detection and monitoring tests that can be the focus of partnering efforts.

Financial Results

Total revenues for the first quarter of FY 2017 were \$5,609,000, compared to \$9,671,000 for the same quarter of the prior fiscal year. The first quarter FY 2017 decrease in revenues was primarily attributed to a decrease in contract manufacturing revenue.

Contract manufacturing revenue from Avid's clinical and commercial biomanufacturing services provided to its third-party clients decreased to \$5,609,000 for the first quarter of FY 2017 compared to \$9,379,000 for the first quarter of FY 2016. The first quarter decrease was primarily due to a backlog at a third-party testing lab and unrelated to product quality that shifted the timing of revenue recognition from the first quarter to the second quarter of fiscal year 2017. The company does not expect this delay to further impact revenue projections for the fiscal year, and the company remains on track to generate revenue in excess of \$20 million in the second quarter FY 2017.

Total costs and expenses for the first quarter of FY 2017 were \$16,691,000, compared to \$23,425,000 for the first quarter of FY 2016. This decrease for the first quarter of FY 2017 was primarily attributable to a decrease in research and development expenses associated with the Phase III SUNRISE trial combined with a decrease in personnel cost and manufacturing costs related to preparing bavituximab for commercial manufacturing.

For the first quarter of FY 2017, research and development expenses decreased 38% to \$8,569,000, compared to \$13,918,000 for the first quarter of FY 2016. In addition, cost of contract manufacturing decreased to \$3,062,000 in the first quarter of FY 2017 compared to \$4,608,000 for the first quarter of FY 2016, primarily due to lower reported revenue compared to the same prior year period. For the first quarter of FY 2017, selling, general and administrative expenses were \$5,060,000 compared to \$4,899,000 for the first quarter of FY 2016.

Peregrine's consolidated net loss attributable to common stockholders was \$12,437,000 or \$0.05 per share, for the first quarter of FY 2017, compared to a net loss attributable to common stockholders of \$15,101,000, or \$0.08 per share, for the same prior year quarter.

Peregrine reported \$44,195,000 in cash and cash equivalents as of July 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 Annual 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 8, 2016, 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 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 the company's current understanding of the potential role of bavituximab in the treatment of various cancers or is otherwise inconclusive, the risk that the final data from the biomarker analysis does not generate any partnership interest, the risk that on-going analysis of SUNRISE trial data, bio-specimen samples and patient characteristics may not identify any subgroup that received clinical benefit from the addition of bavituximab, the risk that the company is unable to secure patent protection or other intellectual property protection for the biomarker analyses, 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 21 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, the risk that the new clinical manufacturing facility will not be operational in mid-2017, or generating revenue in 2017, due to construction or other delays or causes, the risk that the company may not develop, or may experience delays in developing, a commercializable and/or regulatory approvable test derived from the licensed exosome technology, the risk that the company experiences difficulties in developing a test that is able to distinguish between PS-positive exosomes from blood samples of cancer patients and PS-positive exosomes from patients with other diseases or illnesses that express PS-positive exosomes, the risk that the company is unable to generate partnering interest in any cancer diagnostic test that maybe developed from the licensed exosome technology, and the risk that the company is unable to secure patent protection or other intellectual property protection for the cancer test based on the licensed exosome technology. 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 JULY 31,	
	2016	2015
REVENUES:		
Contract manufacturing revenue	\$ 5,609,000	\$ 9,379,000
License revenue	—	292,000
Total revenues	<u>5,609,000</u>	<u>9,671,000</u>
COSTS AND EXPENSES:		
Cost of contract manufacturing	3,062,000	4,608,000
Research and development	8,569,000	13,918,000
Selling, general and administrative	5,060,000	4,899,000
Total costs and expenses	<u>16,691,000</u>	<u>23,425,000</u>
LOSS FROM OPERATIONS	(11,082,000)	(13,754,000)
Interest and other income	25,000	31,000
NET LOSS	<u>\$ (11,057,000)</u>	<u>\$ (13,723,000)</u>
COMPREHENSIVE LOSS	<u>\$ (11,057,000)</u>	<u>\$ (13,723,000)</u>
Series E preferred stock accumulated dividends	(1,380,000)	(1,378,000)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$ (12,437,000)</u>	<u>\$ (15,101,000)</u>
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING		
Basic and diluted	<u>239,595,089</u>	<u>197,317,374</u>
BASIC AND DILUTED LOSS PER COMMON SHARE	<u>\$ (0.05)</u>	<u>\$ (0.08)</u>

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PEREGRINE PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	JULY 31, 2016	APRIL 30, 2016
	<i>Unaudited</i>	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 44,195,000	\$ 61,412,000
Trade and other receivables	7,537,000	2,859,000
Inventories	25,274,000	16,186,000
Prepaid expenses and other current assets	1,235,000	1,351,000
Total current assets	<u>78,241,000</u>	<u>81,808,000</u>
Property and equipment, net	24,261,000	24,302,000
Restricted cash	600,000	600,000
Other assets	2,502,000	2,333,000
TOTAL ASSETS	<u>\$ 105,604,000</u>	<u>\$ 109,043,000</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 9,095,000	\$ 8,429,000
Accrued clinical trial and related fees	6,577,000	7,594,000
Accrued payroll and related costs	3,653,000	5,821,000
Deferred revenue	21,531,000	10,030,000
Customer deposits	21,731,000	24,212,000
Other current liabilities	669,000	1,488,000
Total current liabilities	<u>63,256,000</u>	<u>57,574,000</u>
Deferred rent, less current portion	1,414,000	1,395,000
Commitments and contingencies		
STOCKHOLDERS' EQUITY:		
Preferred stock - \$0.001 par value; authorized 5,000,000 shares; 1,577,440 and 1,577,440 issued and outstanding at July 31, 2016 and April 30, 2016, respectively	2,000	2,000
Common stock-\$0.001 par value; authorized 500,000,000 shares; 241,456,721 and 236,930,485 issued and outstanding at July 31, 2016 and April 30, 2016, respectively	241,000	237,000
Additional paid-in capital	561,024,000	559,111,000
Accumulated deficit	(520,333,000)	(509,276,000)
Total stockholders' equity	<u>40,934,000</u>	<u>50,074,000</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 105,604,000</u>	<u>\$ 109,043,000</u>

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