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PEREGRINE PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

Filed 09/11/17 for the Period Ending 09/11/17

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	TUSTIN, CA, 92780
Telephone	7145086000
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Symbol	PPHM
SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	04/30

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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 11, 2017**

PEREGRINE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**0-17085**	**95-3698422**
(State of other jurisdiction of incorporation)	(Commission File Number)	(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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933(§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).
☐ Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On September 11, 2017, Peregrine Pharmaceuticals, Inc. (the "Company") issued a press release to report the Company's financial results for the first quarter ended July 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.

Important Additional Information

Peregrine intends to file a proxy statement with the Securities and Exchange Commission (SEC) in connection with the solicitation of proxies for Peregrine's 2017 Annual Meeting (Proxy Statement) with an associated WHITE proxy card. Peregrine, its directors and certain of its executive officers will be participants in the solicitation of proxies from stockholders in respect of the 2017 Annual Meeting. Information regarding the names of Peregrine's directors and executive officers and their respective interests in Peregrine by security holdings or otherwise is set forth in the Annual Report on Form 10-K of Peregrine, for the fiscal year ended April 30, 2017, filed with the SEC on July 14, 2017, and Peregrine's proxy statement for the 2016 Annual Meeting, filed with the SEC on August 26, 2016. To the extent holdings of such participants in Peregrine's securities are not reported, or have changed since the amounts described, in the 2016 proxy statement, such changes have been reflected on Initial Statements of Beneficial Ownership on Form 3 or Statements of Change in Ownership on Form 4 filed with the SEC. Details concerning the nominees of Peregrine's Board of Directors for election at the 2017 Annual Meeting will be included in the Proxy Statement. BEFORE MAKING ANY VOTING DECISION, INVESTORS AND STOCKHOLDERS OF THE COMPANY ARE URGED TO READ ALL RELEVANT DOCUMENTS FILED WITH OR FURNISHED TO THE SEC, INCLUDING THE COMPANY'S DEFINITIVE PROXY STATEMENT AND ANY SUPPLEMENTS THERETO, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Investors and stockholders will be able to obtain a copy of the definitive proxy statement and other documents filed by Peregrine free of charge from the SEC's website, www.sec.gov . Peregrine's stockholders will also be able to obtain, without charge, a copy of the definitive Proxy Statement and other relevant filed documents by directing a request by mail to Peregrine, Corporate Secretary's Office, 14282 Franklin Avenue, Tustin, CA 92780, by calling Peregrine's proxy solicitor, MacKenzie Partners, Inc., toll-free at (800) 322-2885, or from Peregrine's website at www.peregrineinc.com .

ITEM 7.01 REGULATION FD DISCLOSURE

On September 11, 2017, 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, 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 September 11, 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: September 11, 2017

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued September 11, 2017.

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Peregrine Pharmaceuticals Reports Financial Results for First Quarter of Fiscal Year 2018 and Recent Developments

-- Avid Bioservices Records Revenues of $27 Million in the First Quarter of FY2018 --

-- Roger Lias, Ph.D., Appointed President of Avid Bioservices as Company Continues Transition to a CDMO Focused Business --

-- Supported by Recent Positive Data, Company is Pursuing Strategic Options for its Research and Development Assets --

TUSTIN, Calif., September 11, 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 through its proprietary R&D pipeline, today announced financial results for the first quarter of fiscal year (FY) 2018 ended July 31, 2017, and provided an update on its contract manufacturing operations, research and development programs, and other corporate highlights.

Highlights Since April 30, 2017

"We have been working diligently toward the transformation from an R&D focused business to a business dedicated to a contract development and manufacturing organization or CDMO. The appointment of Roger Lias, Ph.D., as president of our CDMO subsidiary, Avid Bioservices, and his appointment to Peregrine's board of directors marks an important next step in this transition. Roger is a highly experienced executive with a long track record of success in the CDMO industry, and was an ideal candidate for the position," stated Steven W. King , president and chief executive officer of Peregrine. "We have built a successful commercial CDMO business with an excellent regulatory track record and we look forward to taking Avid to the next level under Roger's leadership. Naturally, job one will be a smooth transition to ensure we continue to support our existing clients while simultaneously working to attract new clients as we look to grow the business on multiple fronts."

Avid Bioservices was established as Peregrine's internal biologics manufacturing and development group, and began formal operations in January 2002. Avid has grown from an internal support operation to a full service CDMO that manufactures bulk drug substance for products that are approved and marketed in over 18 countries by leading biopharma companies. Avid was recently recognized as a leading CDMO by *Life Science Leader* as a recipient of multiple 2017 Contract Manufacturing Leadership Awards for Quality, Reliability, Capabilities, Expertise and Compatibility. Avid has an outstanding regulatory inspection history and state-of-the-art cGMP manufacturing facilities. Mr. King has been president of Avid since its formation in addition to his role as president and CEO of Peregrine Pharmaceuticals since 2003.

Mr. King continued, “As we focus on the CDMO business, we have been evaluating the best option for divesting our R&D assets through licensing or asset sale. The goal being to find a partner that will make a significant short term investment in the bavituximab program in order to validate the subset analysis from the Phase III SUNRISE trial. The subset analysis, which supports the combination of bavituximab with checkpoint inhibitors, is compelling but needs further clinical validation. These data, combined with findings from our collaborators at Memorial Sloan Kettering Cancer Center (MSKCC) supporting combination with cellular therapy and the ongoing trials from our partners at the National Comprehensive Cancer Network (NCCN), have bolstered our drive to find a suitable partner for advancing the bavituximab and PS-exosome diagnostic programs. We are moving forward expeditiously as we recognize the need to move quickly from the R&D standpoint, as well as the establishment of a pure play CDMO with no R&D expenses. We hope to bring this process to completion over the coming months and will update you on our progress.”

Avid Bioservices Highlights

"Avid had a strong first quarter, recognizing revenue of $27 million,” stated Paul Lytle, chief financial officer of Peregrine. "When combined with a 57% decrease in R&D spending and a moderate decrease in SG&A, our net loss for the quarter decreased 89% to $1.2 million. During this transition year where we have seen a lower manufacturing demand from our top two customers, we are still expecting to generate between $50 and $55 million in revenue while we continue to focus on securing new customers and diversifying our customer base as we have added four new customers this calendar year thus far.”

- The company is providing manufacturing revenue guidance for the full FY 2018 of $50 million - $55 million.

- Avid's current manufacturing revenue backlog is $33 million, representing estimated future manufacturing revenue to be recognized under committed contracts. Most of the backlog is expected to be recognized during the remainder of FY 2018.

Research and Development Highlights

ASCO Highlights:
Peregrine researchers presented additional supportive data demonstrating that patients in the bavituximab containing arm who had low baseline PD-L1 expression on tumor cells (i.e., patients typically with poorer response to PD-1/PD-L1 checkpoint inhibitors) lived significantly longer than patients with high baseline PD-L1 expression.

ESMO Highlights:
Clinical investigators and Peregrine researchers presented the final clinical results from the company’s Phase III SUNRISE trial of bavituximab in patients with previously treated locally advanced or metastatic non-squamous non-small cell lung cancer.

As previously reported, study results demonstrated that the addition of bavituximab to docetaxel did not result in improvement of the study’s primary endpoint of overall survival in the intent-to-treat population. However, a subgroup analysis on the final dataset demonstrated that for bavituximab plus docetaxel patients who received subsequent immunotherapy, the median overall survival was not yet reached. This compared to a median overall survival of 12.6 months for patients who received placebo plus docetaxel, and subsequent immunotherapy [HR = 0.46; p = 0.006].

NCCN Highlights:
The three clinical trials under the collaboration with the NCCN are advancing as planned.

- Massachusetts General Hospital Cancer Center—Phase I/II Clinical Trial of Bavituximab with Radiation and Temozolomide for Patients with Newly Diagnosed Glioblastoma. Patient dosing was initiated in September 2017.

- Moffitt Cancer Center—A Phase I Trial of Sorafenib and Bavituximab Plus Stereotactic Body Radiation Therapy for Unresectable Hepatitis C Associated Hepatocellular Carcinoma. This trial is open for enrollment.

- 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 expected to be initiated by the end of the calendar year 2017.

PS Exosome Technology Highlights:
The company continues to make progress with its PS exosome diagnostic technology that is designed to detect and monitor cancer. The assay has been successfully optimized and we are evaluating options to license, partner, or sell this technology.

Financial Highlights and Results

- Contract manufacturing revenue from Avid's clinical and commercial biomanufacturing services was $27,077,000 for the first quarter of FY 2018 compared to $ 5,609,000 for the first quarter of FY 2017. This represents total revenue growth of 383% for FY 2018 compared to the same prior year period. It is important to note that the $27 million included the shipment of $10 million in product, which was held over from the fourth quarter of 2017 due to delays in shipping at the customer's request. The first quarter increase was primarily attributed to an increase in demand for contract manufacturing services associated with process validation activities in addition to the greater number of manufacturing runs shipped during the quarter.

- Total costs and expenses for the first quarter of FY 2018 were $28,306,000, compared to $16,691,000 for the first quarter of FY 2017. Research and development expenses decreased 57% to $3,645,000, compared to $ 8,569,000 for the first quarter of FY 2017 .

- Cost of contract manufacturing increased to $20,448,000 in the first quarter of FY 2018 compared to $ 3,062,000 for the first quarter of FY 2017. This increase is 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 was idle capacity due to lower demand and unavailable capacity during the installation of the new 2,000 liter bioreactors combined with a higher percentage of revenue related to pass through charges, such as raw materials, that are recorded as revenue at cost plus a nominal mark-up, thereby lowering the overall gross margin. During the current quarter, 38% of our revenue was related to pass-through charges versus 20% in the same prior year quarter.

- For the first quarter of FY 2018, selling, general and administrative expenses decreased to $4,213,000 compared to $ 5,060,000 for FY 2017.

- Peregrine's consolidated net loss attributable to common stockholders was $2,647,000 or $0.06 per share, for the first quarter of FY 2018, compared to a net loss attributable to common stockholders of $ 12,437,000 , or $0.36 per share, for the same prior year quarter.

- Peregrine reported $37,256,000 in cash and cash equivalents as of July 31, 2017, compared to $46,799,000 at fiscal year ended April 30, 2017.

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 11, 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 its proprietary R&D pipeline. 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 the company will not be successful in licensing or selling bavituximab and/or any other R&D assets over the coming months, the risk that the company will not realize any current monetary value for its research and development assets; the risk that the company will be unable to monetize bavituximab or any other R&D assets and will need to cease further development of some or all R&D assets due to insufficient financial resources, the risk that the company may not have or raise adequate financial resources from equity financings and/or Avid's manufacturing operations to enable it to continue as a going concern, the risk that reductions in demand from Avid's two significant customers due to their regulatory or other delays will not recover during the current fiscal year resulting in idle capacity, underutilization of manufacturing facilities, and lower than anticipated revenues, the risk that the company will need to raise additional capital during the fiscal year in order to fund Avid's operations, the risk that the company does not achieve profitability, the risk that Avid may experience technical difficulties in processing customer orders which could delay delivery of products to customers, revenue recognition and receipt of payment, and the risk that one or more existing Avid customers terminates its contract prior to completion or reduces or delays its demand for manufacturing services. 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, 2017 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,	
	2017	**2016**
Contract manufacturing revenue	$ 27,077,000	$ 5,609,000
COSTS AND EXPENSES:		
Cost of contract manufacturing	20,448,000	3,062,000
Research and development	3,645,000	8,569,000
Selling, general and administrative	4,213,000	5,060,000
Total costs and expenses	28,306,000	16,691,000
LOSS FROM OPERATIONS	(1,229,000)	(11,082,000)
OTHER INCOME (EXPENSE):		
Interest and other income	27,000	25,000
Interest and other expense	(3,000)	–
NET LOSS	$ (1,205,000)	$ (11,057,000)
COMPREHENSIVE LOSS	$ (1,205,000)	$ (11,057,000)
Series E preferred stock accumulated dividends	(1,442,000)	(1,380,000)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	$ (2,647,000)	$ (12,437,000)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING		
Basic and diluted [1]	44,773,727	34,227,870
BASIC AND DILUTED LOSS PER COMMON SHARE [1]	$ (0.06)	$ (0.36)

(1) All share and per share amounts of our common stock for all periods presented have been retroactively adjusted to reflect the one-for-seven reverse stock split of our issued and outstanding common stock, which took effect with the opening of trading on July 10, 2017.

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PEREGRINE PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	JULY 31, 2017	APRIL 30, 2017
	Unaudited	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 37,256,000	$ 46,799,000
Trade and other receivables	7,884,000	7,742,000
Inventories	24,235,000	33,099,000
Prepaid expenses	1,388,000	1,460,000
Total current assets	70,763,000	89,100,000
Property and equipment, net	24,399,000	23,674,000
Restricted cash	1,150,000	1,150,000
Other assets	3,963,000	4,188,000
TOTAL ASSETS	$ 100,275,000	$ 118,112,000
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 4,013,000	$ 5,779,000
Accrued clinical trial and related fees	4,812,000	4,558,000
Accrued payroll and related costs	4,844,000	6,084,000
Deferred revenue	13,433,000	28,500,000
Customer deposits	14,322,000	17,017,000
Other current liabilities	963,000	993,000
Total current liabilities	42,387,000	62,931,000
Deferred rent, less current portion	1,880,000	1,599,000
Commitments and contingencies		
STOCKHOLDERS' EQUITY [(1)] :		
Preferred stock—$0.001 par value; authorized 5,000,000 shares; 1,647,760 issued and outstanding at July 31, 2017 and April 30, 2017, respectively	2000	2000
Common stock—$0.001 par value; authorized 500,000,000 shares; 45,094,154 and 44,014,040 issued and outstanding at July 31, 2017 and April 30, 2017, respectively	45,000	44,000
Additional paid-in capital	594,482,000	590,971,000
Accumulated deficit	(538,521,000)	(537,435,000)
Total stockholders' equity	56,008,000	53,582,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 100,275,000	$ 118,112,000

(1) All share and per share amounts of our common stock for all periods presented have been retroactively adjusted to reflect the one-for-seven reverse stock split of our issued and outstanding common stock, which took effect with the opening of trading on July 10, 2017.

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