

PEREGRINE PHARMACEUTICALS INC

FORM 8-K (Current report filing)

Filed 09/03/09 for the Period Ending 09/03/09

Address	14282 FRANKLIN AVE TUSTIN, CA 92780
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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 3, 2009**

PEREGRINE PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of other jurisdiction
of incorporation)

0-17085
(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 3, 2009, Peregrine Pharmaceuticals, Inc. issued a press release to report the Company's financial results for the first quarter ended July 31, 2009. 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 3, 2009, at 11:30 a.m. EDT/8:30 a.m. PDT, the Company hosted a conference call to discuss its First Quarter Fiscal Year 2010 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 3, 2009

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 3, 2009

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

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release issued September 3, 2009

PEREGRINE

Pharmaceuticals, Inc.

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**PEREGRINE PHARMACEUTICALS REPORTS FINANCIAL RESULTS FOR THE
FIRST QUARTER OF FISCAL YEAR 2010**

***--Advances Achieved in All Six Bavituximab and Cotara[®] Cancer Clinical Studies--
--Total Revenue Increased 345% to \$6.75 Million, Avid Revenue Increased 74% and Net Loss
Declined 52% Compared to Prior Year Quarter--***

TUSTIN, Calif., September 3, 2009 -- Peregrine Pharmaceuticals, Inc. (Nasdaq: PPHM) today announced financial results for the first quarter of fiscal year (FY) 2010 ended July 31, 2009. Total revenues for the first quarter of FY 2010 increased 345% to \$6,750,000, compared to \$1,517,000 for the comparable prior year quarter. This increase was primarily generated from increased government contract revenue and from increased sales by Avid Bioservices, the company's wholly owned contract manufacturing subsidiary.

Avid generated manufacturing revenues of \$2,070,000 for the first quarter of FY 2010, compared to \$1,193,000 for the comparable prior year quarter, an increase of 74%. The increase in Avid revenues reflects increased manufacturing services provided to third-party customers during the quarter. In addition to manufacturing revenues, Peregrine generated revenues from services provided under its contract with the U.S. Defense Threat Reduction Agency for the Transformational Medical Technologies Initiative (TMTI) to evaluate bavituximab as a potential broad-spectrum treatment for viral hemorrhagic fever infections. Government contract revenues were \$4,671,000 for the first quarter of FY 2010, compared to \$324,000 for the prior year quarter when the government contract work had just begun.

Total costs and expenses in the first quarter of FY 2010 were \$8,940,000, compared to \$6,677,000 in the first quarter of FY 2009, an increase of 34%. Costs of contract manufacturing, which increased to \$1,073,000 in the first quarter of FY 2010 from \$903,000 in the prior year quarter, were directly driven by the increase in Avid revenue. Research and development (R&D) expenses increased to \$6,074,000 in the first quarter of FY 2010, compared to \$4,068,000 in the prior year quarter, an increase of 49%, primarily due to increased R&D costs incurred under the government contract combined with increased costs associated with the advancement of Peregrine's clinical programs. Selling, general, and administrative (SG&A) expenses increased only slightly in the first quarter of FY 2010 to \$1,793,000, compared to \$1,706,000 in the first quarter of FY 2009.

The consolidated net loss of \$2,428,000 or \$0.01 per basic and diluted share in the first quarter of FY 2010 represented a 52% decrease compared to the consolidated net loss of \$5,086,000, or \$0.02 per basic and diluted share for the same prior year period. At July 31, 2009, the company had \$12,778,000 in cash and cash equivalents.

"I am pleased to report that the momentum we achieved in all elements of our business in the last fiscal year has continued into fiscal year 2010," said Steven W. King, president and CEO of Peregrine. "We have continued to successfully advance the bavituximab and Cotara cancer clinical trials that are the key value drivers for Peregrine. Since the start of the new fiscal year, we completed patient enrollment in two bavituximab clinical trials and presented positive interim data from both studies at ASCO, in addition to reporting positive clinical data from our ongoing Cotara clinical studies at the Society of Nuclear Medicine 2009 Annual Meeting. We also continued to make excellent progress in our work under our TMTI government research contract worth up to \$44.4 million to develop bavituximab for the treatment of viral hemorrhagic fevers (VHF), while our collaborators at UT Southwestern Medical Center were awarded a significant grant from the National Institute for Allergies and Infectious Diseases (NIAID) for an expanded study of additional PS-targeting antibodies as potential treatments for VHF. The awarding of the new NIAID contract is another important outside validation of the broad-spectrum anti-viral potential of our PS-targeting technology platform."

Mr. King added, “In all three of our bavituximab cancer Phase II trials, bavituximab in combination with chemotherapy has demonstrated encouraging signs of anti-tumor activity in patients with advanced breast and lung cancers. All three trials surpassed the requisite efficacy criteria for expansion of patient enrollment. These trials, along with recent completion of planned enrollment in our U.S. Phase I bavituximab cancer study, are helping to set the stage for advancing bavituximab toward additional clinical trials. As we plan for these trials, we are very pleased to be working with noted cancer clinical researcher Dr. Bruce Chabner, clinical director of Massachusetts General Hospital Cancer Center, who is serving as a clinical advisor on the design of these next clinical trials.”

Mr. King continued, “During the first quarter, we completed an agreement with Affitech A/S, sublicensing them certain rights to develop the selective anti-VEGF antibodies produced in an earlier collaboration. This agreement provides us with upfront and potential milestone payments and royalties, and is an excellent example of how we intend to continue leveraging the non-core technologies that are part of Peregrine’s asset base. We also reported outstanding financial results for the quarter, growing revenues 345% and reducing our net loss by more than half. Our revenue growth reflects the success of our federal government R&D contract work and continued growth in our contract manufacturing business, Avid. We announced last week that we have expanded the management team at Avid to help manage and sustain this growth.”

Mr. King concluded, “These achievements since the end of the last fiscal year have enabled us to continue to build significant value in our oncology clinical pipeline, to grow the value of our contract manufacturing business and to realize immediate value from our bavituximab anti-viral platform through our TMTI government contract work. Planning for the exciting next phase of our bavituximab oncology program has already begun. With seven ongoing clinical trials on track to generate additional data in the coming months, Avid Bioservices focused on continued growth and our government-supported anti-viral research contract proceeding well, we believe Peregrine is well positioned to continue building the momentum we have achieved in the first quarter of this new fiscal year.”

FY 2010 Highlights to Date

Bavituximab Anti-Cancer Program

Peregrine reported progress in all four ongoing trials in its bavituximab cancer program, including its three Phase II trials:

- Completed enrollment of the planned 46 patients in a Phase II trial evaluating bavituximab in combination with docetaxel in advanced breast cancer patients. As reported in an oral presentation at the 2009 ASCO Annual Meeting, 10 of 14, or 71% of evaluable patients in the initial cohort demonstrated an objective tumor response according to RECIST criteria. These early data from the study compare favorably with historical data with chemotherapy alone. Recent analysis showed the median progression free survival of patients enrolled in the first part of the study was 7.4 months, a promising early result. Patient dosing and follow-up in this trial are continuing.
- Reported that in a Phase II trial evaluating bavituximab in combination with carboplatin and paclitaxel in non-small cell lung cancer (NSCLC) patients with locally advanced or metastatic disease, 11 of 17, or almost 65% of evaluable patients in the initial cohort, achieved an objective tumor response according to RECIST criteria. These early results compare very favorably with historical data with chemotherapy alone and are especially encouraging in this hard-to-treat cancer. Patient enrollment and dosing are continuing in the expansion stage of the trial, which will enroll a total of 49 patients overall.
- In a Phase II trial evaluating bavituximab in combination with carboplatin and paclitaxel in advanced breast cancer patients, Peregrine reported that nine of 14, or 64% of evaluable patients in the initial cohort of this trial achieved an objective tumor response according to RECIST criteria. These data exceeded the pre-specified endpoint needed to expand the trial. Patient enrollment and dosing are continuing in the expansion stage of the trial, which will enroll a total of 46 patients overall.
- Completed planned patient enrollment in a Phase I trial evaluating bavituximab as monotherapy in patients with advanced refractory cancers. At the 2009 ASCO Annual Meeting, study researchers reported that bavituximab had demonstrated acceptable safety and that a maximum tolerated dose was not reached, even at the highest planned dose level.

- Announced that the ASCO Research Foundation awarded one of its 2009 Career Development Awards to a researcher at the University of Texas Southwestern Medical Center for a study of the biologic effects of bavituximab and chemotherapy in patients with advanced lung cancer.
- Announced that noted cancer researcher Bruce Chabner, M.D., will serve as a clinical advisor on the design of clinical trials for the bavituximab and Cotara cancer program. Dr. Chabner is currently the clinical director of Massachusetts General Hospital (MGH) Cancer Center, chief of hematology and oncology at MGH and a professor of medicine at Harvard Medical School. Previously, Dr. Chabner had a distinguished 25-year career at the National Cancer Institute.

Bavituximab Anti-Viral Program

The company continued to advance the bavituximab anti-viral program:

- Continued to execute under a five-year contract potentially worth up to \$44.4 million with the Department of Defense's Defense Threat Reduction Agency for the Transformational Medical Technologies Initiative (TMTI) to assess bavituximab and other PS-targeting antibodies for biodefense applications against viral hemorrhagic fevers.
- Announced that research colleagues at the University of Texas Southwestern Medical Center received a two-year \$763,000 grant from the U.S. National Institute of Allergy and Infectious Diseases (NIAID) for research expanding studies of anti-PS antibodies as potential treatments for viral hemorrhagic fever infections.

Cotara® Brain Cancer Program

- Reported that patient enrollment in the Cotara dosing and dosimetry trial at U.S. brain cancer centers was nearing completion, and that patients in the initial two cohorts of the study have all either met or exceeded the expected median survival time of six months for recurrent glioblastoma multiforme (GBM) patients.
- Researchers presented interim data on 10 GBM patients at first relapse from the ongoing Phase II study at the XIV World Congress of Neurological Surgery Annual Meeting showing that Cotara appeared well tolerated and demonstrated encouraging signs of efficacy in this subset of patients. The interim median recurrence-free survival of these patients was 33 weeks and the interim median overall survival was 41 weeks. This compares favorably with historical data on expected survival for patients with GBM, which is approximately 24 weeks from time of disease recurrence. Based on this data, the study authors conclude that Cotara appears to be feasible, tolerable and has encouraging signs of efficacy in recurrent GBM patients.
- Presented data at the Society of Nuclear Medicine 2009 Annual Meeting showing that Cotara specifically localizes to brain tumors at high concentrations with minimal radiation exposure to other organs. This data affirms a key safety attribute of Cotara—its ability to precisely target tumors. Researchers also reported that more than 65 patients with recurrent GBM had now received Cotara. Localization and accumulation of the drug to the tumor have been excellent and longer-term survivors (greater than one year from the time of Cotara treatment) have been observed in all of the trials, with some GBM patients now alive more than 8.5 years after treatment with Cotara.

Other Developments

- Entered into a licensing agreement with Affitech A/S for Peregrine's preclinical anti-VEGF (vascular endothelial growth factor) antibody program. Affitech has licensed exclusive worldwide rights to develop and commercialize products under Peregrine's selective anti-VEGF intellectual property portfolio. Affitech is responsible for future development and potential product commercialization. Peregrine receives an upfront payment, research fees and future milestone payments.

Conference Call

The company will host a conference call today, September 3, 2009 at 11:30 a.m. EDT/8:30 a.m. PDT to discuss its First Quarter FY 2010 financial results.

To listen to a live broadcast of the call over the Internet or to review the archived call, please visit: www.peregrineinc.com. The webcast will be archived on Peregrine's website for approximately 30 days.

To listen to the conference call via telephone, please call the following number approximately 10 minutes prior to the scheduled start time and request to join the Peregrine Pharmaceuticals call: (800) 860-2442. A telephonic replay of the conference call will be available starting approximately one hour after the conclusion of the call through September 10, 2009 by calling (877) 344-7529, passcode 431883#.

About Peregrine Pharmaceuticals

Peregrine Pharmaceuticals, Inc. is a biopharmaceutical company with a portfolio of innovative monoclonal antibodies in clinical trials for the treatment of cancer and serious viral infections. The company is pursuing three separate clinical programs in cancer and hepatitis C virus infection with its lead product candidates bavituximab and Cotara[®]. Peregrine also has in-house manufacturing capabilities through its wholly owned subsidiary Avid Bioservices, Inc. (www.avidbio.com), which provides development and biomanufacturing services for both Peregrine and outside customers. Additional information about Peregrine can be found at www.peregrineinc.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 company may experience delays in clinical trial patient enrollment, the results of future clinical trials may not correlate with the results from prior clinical and preclinical studies, the risk that the rate of objective tumor response for the expansion stages of the company's three Phase II trials will not be consistent with the objective tumor responses experienced in the first stage of the respective Phase II trials, the risk that the standard chemotherapy response rate will not be improved as a result of the combination therapy with the inclusion of bavituximab, the risk that the company will not be able to raise additional capital under its "At the Market" sales agreement, the risk that Avid's revenue growth may slow or decline, the risk that Avid may experience technical difficulties in processing customer orders which could delay delivery of products to customers and receipt of payment, the risk that one or more existing Avid customers terminates its contract prior to completion, the risk that the company does not receive all of its funding under the DTRA contract, the risk that future protocol submissions may not be approved and the risk that the company may not be able to monetize any of its assets. It is important to note that the company's actual results could differ materially from those in any such forward-looking statements. Factors that could cause actual results to differ materially include, but are not limited to, uncertainties associated with completing preclinical and clinical trials for our technologies; the early stage of product development; the significant costs to develop our products as all of our products are currently in development, preclinical studies or clinical trials; obtaining additional financing to support our operations and the development of our products; obtaining regulatory approval for our technologies; anticipated timing of regulatory filings and the potential success in gaining regulatory approval and complying with governmental regulations applicable to our business. Our business could be affected by a number of other factors, including the risk factors listed from time to time in the Company's SEC reports including, but not limited to, the annual report on Form 10-K for the year ended April 30, 2009. 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 .

-financial tables to follow-

PEREGRINE PHARMACEUTICALS, INC.**CONDENSED CONSOLIDATED BALANCE SHEETS**

	JULY 31, 2009	APRIL 30, 2009
	<i>Unaudited</i>	
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 12,778,000	\$ 10,018,000
Trade and other receivables	1,715,000	1,770,000
Government contract receivables	1,449,000	1,944,000
Inventories, net	6,177,000	4,707,000
Debt issuance costs, current portion	202,000	229,000
Prepaid expenses and other current assets, net	<u>991,000</u>	<u>1,466,000</u>
Total current assets	23,312,000	20,134,000
PROPERTY:		
Leasehold improvements	675,000	675,000
Laboratory equipment	4,189,000	4,180,000
Furniture, fixtures and office equipment	<u>902,000</u>	<u>902,000</u>
	5,766,000	5,757,000
Less accumulated depreciation and amortization	<u>(4,192,000)</u>	<u>(4,076,000)</u>
Property, net	1,574,000	1,681,000
OTHER ASSETS:		
Debt issuance costs, less current portion	102,000	142,000
Other assets	<u>1,225,000</u>	<u>1,170,000</u>
Total other assets	1,327,000	1,312,000
TOTAL ASSETS	<u>\$ 26,213,000</u>	<u>\$ 23,127,000</u>

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PEREGRINE PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (continued)

	JULY 31, 2009	APRIL 30, 2009
	<i>Unaudited</i>	
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 3,395,000	\$ 3,518,000
Accrued clinical trial site fees	773,000	955,000
Accrued legal and accounting fees	519,000	667,000
Accrued royalties and license fees	170,000	182,000
Accrued payroll and related costs	1,735,000	1,580,000
Notes payable, current portion and net of discount	1,822,000	1,465,000
Deferred revenue	5,755,000	3,776,000
Deferred government contract revenue	2,332,000	3,871,000
Customer deposits	966,000	2,287,000
Other current liabilities	<u>625,000</u>	<u>563,000</u>
Total current liabilities	18,092,000	18,864,000
Notes payable, less current portion and net of discount	2,743,000	3,208,000
Other long-term liabilities	153,000	154,000
Commitments and contingencies		
STOCKHOLDERS' EQUITY:		
Preferred stock-\$0.001 par value; authorized 5,000,000 shares; non-voting; nil shares outstanding	-	-
Common stock-\$0.001 par value; authorized 325,000,000 shares; outstanding – 236,968,914 and 227,688,555, respectively	237,000	227,000
Additional paid-in capital	254,776,000	248,034,000
Accumulated deficit	<u>(249,788,000)</u>	<u>(247,360,000)</u>
Total stockholders' equity	<u>5,225,000</u>	<u>901,000</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 26,213,000</u>	<u>\$ 23,127,000</u>

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PEREGRINE PHARMACEUTICALS, INC.**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

	THREE MONTHS ENDED	
	July 31, 2009	July 31, 2008
	<i>Unaudited</i>	<i>Unaudited</i>
REVENUES:		
Contract manufacturing revenue	\$ 2,070,000	\$ 1,193,000
Government contract revenue	4,671,000	324,000
License revenue	9,000	-
Total revenues	<u>6,750,000</u>	<u>1,517,000</u>
COSTS AND EXPENSES:		
Cost of contract manufacturing	1,073,000	903,000
Research and development	6,074,000	4,068,000
Selling, general and administrative	1,793,000	1,706,000
Total costs and expenses	<u>8,940,000</u>	<u>6,677,000</u>
LOSS FROM OPERATIONS	<u>(2,190,000)</u>	<u>(5,160,000)</u>
OTHER INCOME (EXPENSE):		
Interest and other income	40,000	75,000
Interest and other expense	<u>(278,000)</u>	<u>(1,000)</u>
NET LOSS	<u>\$ (2,428,000)</u>	<u>\$ (5,086,000)</u>
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING	<u>234,043,957</u>	<u>226,210,617</u>
BASIC AND DILUTED LOSS PER COMMON SHARE	<u>\$ (0.01)</u>	<u>\$ (0.02)</u>

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