

PEREGRINE PHARMACEUTICALS INC

FORM 8-K (Current report filing)

Filed 07/14/17 for the Period Ending 07/14/17

Address	14282 FRANKLIN AVE TUSTIN, CA 92780
Telephone	7145086000
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Symbol	PPHM
SIC Code	2834 - Pharmaceutical Preparations
Industry	Pharmaceuticals
Sector	Healthcare
Fiscal Year	04/30

**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): **July 14, 2017**

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))

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 July 14, 2017, Peregrine Pharmaceuticals, Inc. (the “Company”) issued a press release to report the Company’s financial results for the fourth quarter and fiscal year ended April 30, 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 July 14, 2017, at 4:30 p.m. EDT/1:30 p.m. PDT, the Company will host a conference call to discuss its fourth quarter and fiscal year ended April 30, 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 July 14, 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: July 14, 2017

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release issued July 14, 2017



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Peregrine Pharmaceuticals Reports Financial Results for Quarter and Fiscal Year Ended April 30, 2017 and Recent Developments

-- Avid Achieves Year-Over-Year Topline Revenue Growth of 30% Exceeding \$57 Million --

-- Recent Presentation Supports Baviximab's Potential to Improve Clinical Outcome for Immune Checkpoint Inhibitors --

TUSTIN, Calif., July 14, 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 fourth quarter and fiscal year (FY) ended April 30, 2017, and provided an update on its contract manufacturing operations, research and development programs, and other corporate highlights.

Highlights Since January 31, 2017

“We are very pleased to announce that the business recorded its highest annual revenue to date during fiscal 2017,” stated Steven W. King, president and chief executive officer of Peregrine, and president of Avid Bioservices. “While we are happy to report continued year-over-year revenue growth, we are projecting revenues for FY 2018 to be similar with FY 2017 due to recent changes in the forecast of a large customer and a delayed regulatory filing for another customer. We believe this is a temporary lull and remain confident that Avid is in a strong position for continued growth in the future.” Mr. King continued, “An important part of continuing revenue growth and reducing risk for the business is to attract new customers. On that front, we have recently signed four new customers that we expect to contribute to top-line revenue in FY 2018 and into the future. In addition, we successfully completed three process validation campaigns this fiscal year for existing third-party customers which we believe may significantly contribute to future revenue as these customers move toward building inventory for their potential launch, and commercial supply.”

“We are also continuing to take other important steps to ensure Avid’s growth in the coming years. As part of this effort, we have recently installed two new 2,000 liter bioreactors in our Myford facility, and we already have commitments for part of this capacity. Due to its state-of-the-art and modular design, there remains potential to install additional bioreactors in Myford, which will allow us to continue growing the business within our current facilities.”

“Turning to the Peregrine business, we were able to generate some of the most compelling baviximab data to date, further supporting the combination of baviximab and checkpoint inhibitors even while reducing R&D spending by over 50% in FY 2017. The clinical findings came from the comprehensive analysis of maturing Phase III SUNRISE data while impressive preclinical results came from our collaborators at Memorial Sloan Kettering Cancer Center (MSKCC). The researchers at MSKCC presented promising preclinical data combining PS-targeting with adoptive T cell transfer therapy which may support the combination of baviximab with CAR-T cell immunotherapy in the future.”

“Both Peregrine and Avid have achieved important milestones in recent quarters. The success of Avid and its continued revenue growth with the compelling data we have seen from the Phase III SUNRISE trial have led us to explore various strategic options that we believe will enable us to enhance stockholder value for all stockholders, including the possible separation of these two distinct businesses.”

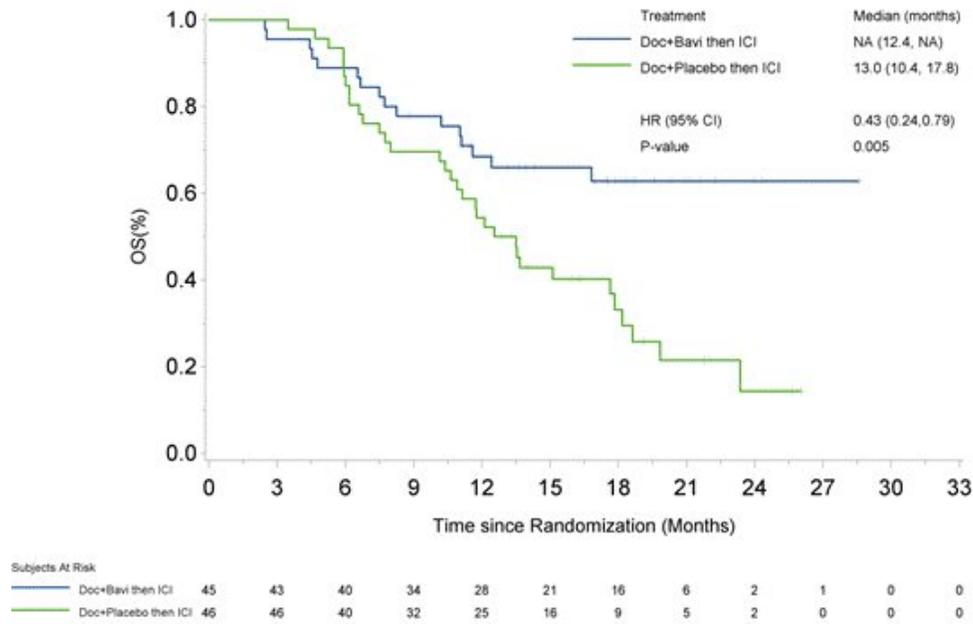
Research and Development Highlights

"The most compelling data to date from the Phase III SUNRISE trial was presented at AACR and together with the PD-L1 results presented at ASCO this year add to the growing body of data supporting the further development of bavituximab with checkpoint inhibitors," said Joseph Shan, vice president of clinical and regulatory affairs at Peregrine.

AACR Highlights:

In a subgroup analysis, Peregrine researchers looked at the outcome of 91 patients that were enrolled in the Phase III SUNRISE trial that were subsequently treated with anti-PD-1/PD-L1 immune checkpoint inhibitors ("ICI's") post study treatments. The results from this analysis demonstrated that the patients who received docetaxel plus bavituximab (Doc+Bavi) and subsequent ICI had not yet reached median overall survival ("mOS") compared to mOS of 13.0 months for patients who received docetaxel plus placebo (Doc+Placebo) (hazard ratio [HR], 0.43; p=0.005). The statistically significant difference between the two arms in the trial provides strong rationale for combining bavituximab with ICI's and supports the hypothesis that bavituximab may modulate the tumor microenvironment to enhance the anti-tumor activity of ICI's.

Overall Survival in Phase III SUNRISE Subgroup Receiving Subsequent Immune Checkpoint Inhibitors



Modified from Kallinteris NL et. al., AACR 2017

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. These data further support the hypothesis that bavituximab may modulate the tumor microenvironment to complement and enhance the anti-tumor activity of ICI's.

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 Baviximab with Radiation and Temozolomide for Patients with Newly Diagnosed Glioblastoma. This trial is open for enrollment.
- Moffitt Cancer Center—A Phase I Trial of Sorafenib and Baviximab 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 Baviximab 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.

Preclinical Highlights:

Researchers from Memorial Sloan Kettering Cancer Center (MSKCC) presented a preclinical study evaluating the anti-tumor activity and toxicities of adoptive T cell transfer therapy in combination with either PS-targeting antibodies or anti-OX40 antibodies in mice with advanced melanomas. Whereas PS-targeting and anti-OX40 demonstrated comparable tumor regression when administered in combination with transferred adoptive T cells, only the PS-targeting combination achieved these results without any off-target toxicities. In contrast, the anti-OX40 treatment combination triggered off-target side effects.

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 currently preparing to generate additional data by testing human samples. Such data will be important to partnering discussions.

Avid Bioservices Highlights

"FY 2017 was a strong year for Avid Bioservices with year-over-year revenue growth of 30% compared to FY 2016. The company recognized revenue of \$17.9 million for the fourth quarter and \$57.6 million for the full fiscal year," stated Paul Lytle, chief financial officer of Peregrine. "While we missed our revenue guidance of \$60 to \$65 million, we were ready to ship a number of process validation runs which were delayed due to events outside our control. This delay has caused approximately \$10 million in manufacturing revenue to shift from fiscal year 2017 to fiscal year 2018."

- The company is providing manufacturing revenue guidance for the full FY 2018 of \$50 million - \$55 million.
- Avid's current manufacturing revenue backlog is \$58 million, representing estimated future manufacturing revenue to be recognized under committed contracts. Most of the backlog is expected to be recognized during FY 2018.

Financial Highlights and Results

- During the fourth quarter of FY 2017, we recorded total revenues of \$17,904,000 as compared to \$ 18,783,000 in the fourth quarter of the prior FY. For FY 2017, we achieved total revenues of \$57,630,000 as compared to \$44,686,000 for FY 2016. This represents total revenue growth of 29% for FY 2017 compared to the same prior year period.
- Contract manufacturing revenue from Avid's clinical and commercial biomanufacturing services was \$17,904,000 for the fourth quarter of FY 2017 compared to \$18,783,000 for the fourth quarter of FY 2016. For the year, revenue increased 30% to \$57,630,000 for FY 2017 compared to \$44,357,000 for FY 2016. The fiscal year increase was primarily attributed to an increase in demand for contract manufacturing services associated with process validation activities. Current committed manufacturing backlog for Avid is approximately \$58 million, covering services to be provided during FY 2018 and into FY 2019. Based on this current backlog, Peregrine expects contract manufacturing revenue for FY 2018 to be between \$50 and \$55 million.
- Total costs and expenses for the fourth quarter of FY 2017 were \$23,208,000, compared to \$30,698,000 for the fourth quarter of FY 2016. For FY 2017, total costs and expenses were \$85,890,000 compared to \$101,046,000 for FY 2016. For the fourth quarter of FY 2017, research and development expenses decreased 59% to \$6,717,000, compared to \$ 16,265,000 for the fourth quarter of FY 2016. For FY 2017, research and development expenses decreased 52% to \$28,297,000 compared to \$59,529,000 for FY 2016.

- Cost of contract manufacturing increased to \$11,782,000 in the fourth quarter of FY 2017 compared to \$ 9,721,000 for the fourth quarter of FY 2016, and to \$38,259,000 for the full FY 2017 as compared to \$ 22,966,000 for the full FY 2016. These increases are 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 overhead cost of operating the new Myford facility as well as higher labor cost associated with performing process validation runs combined with lower utilization of available capacity. For the fourth quarter of FY 2017, selling, general and administrative expenses decreased slightly to \$4,709,000 compared to \$ 4,712,000 for FY 2016. For FY 2017 selling, general and administrative expenses increased to \$19,334,000 compared to \$18,551,000 for FY 2016. The full-year increase is primarily due to the company's growing manufacturing business.
- Peregrine's consolidated net loss attributable to common stockholders was \$6,714,000 or \$0.16 per share, for the fourth quarter of FY 2017, compared to a net loss attributable to common stockholders of \$ 13,264,000 , or \$0.40 per share, for the same prior year quarter. For FY 2017, net loss attributable to common stockholders was \$32,799,000 , or \$0.88 per share, compared to \$60,136,000 , or \$1.95 per share, for FY 2016.
- Peregrine reported \$46,799,000 in cash and cash equivalents as of April 30, 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 Annual Report on Form 10-K, which will be filed with the Securities and Exchange Commission today.

Conference Call

Peregrine will host a conference call and webcast this afternoon, July 14, 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 a future clinical trial combining bavituximab with an immune checkpoint inhibitor may not generate statistically significant data, data consistent with the data presented at AACR regarding SUNRISE patients who were treated with bavituximab and subsequently treated with immune checkpoint inhibitors or data supporting the theory that bavituximab modulates the tumor microenvironment to complement and enhance anti-tumor activity of immune checkpoint inhibitors, the risk that one or more of the NCCN grant funded investigator-initiated clinical studies may experience 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 enable it to continue as a going concern, or to fund the further development of bavituximab or further development of PS exosome diagnostic technology, the risk that data from further testing of the PS exosome diagnostic with human samples will not support further development, commercialization or contemplated partnering discussions, the risk that Avid's revenue growth may slow or decline, 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, the risk that one or more existing Avid customers terminates its contract prior to completion or reduces or delays its demand for manufacturing services, and the risk that commencement of construction of the new manufacturing facility will be delayed indefinitely due to a lack of customer demand and/or 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, 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.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	THREE MONTHS ENDED		TWELVE MONTHS ENDED	
	APRIL 30,		APRIL 30,	
	2017	2016	2017	2016
	<i>Unaudited</i>	<i>Unaudited</i>		
REVENUES:				
Contract manufacturing revenue	\$ 17,904,000	\$ 18,783,000	\$ 57,630,000	\$ 44,357,000
License revenue	—	—	—	329,000
Total revenues	17,904,000	18,783,000	57,630,000	44,686,000
COSTS AND EXPENSES:				
Cost of contract manufacturing	11,782,000	9,721,000	38,259,000	22,966,000
Research and development	6,717,000	16,265,000	28,297,000	59,529,000
Selling, general and administrative	4,709,000	4,712,000	19,334,000	18,551,000
Total costs and expenses	23,208,000	30,698,000	85,890,000	101,046,000
LOSS FROM OPERATIONS	(5,304,000)	(11,915,000)	(28,260,000)	(56,360,000)
OTHER INCOME (EXPENSE):				
Interest and other income	37,000	31,000	108,000	722,000
Interest and other expense	(5,000)	—	(7,000)	(14,000)
NET LOSS	\$ (5,272,000)	\$ (11,884,000)	\$ (28,159,000)	\$ (55,652,000)
COMPREHENSIVE LOSS	\$ (5,272,000)	\$ (11,884,000)	\$ (28,159,000)	\$ (55,652,000)
Series E preferred stock accumulated dividends	(1,442,000)	(1,380,000)	(4,640,000)	(4,484,000)
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ (6,714,000)	\$ (13,264,000)	\$ (32,799,000)	\$ (60,136,000)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING:				
Basic and Diluted ⁽¹⁾	42,141,720	33,478,863	37,109,493	30,895,089
BASIC AND DILUTED LOSS PER COMMON SHARE ⁽¹⁾	\$ (0.16)	\$ (0.40)	\$ (0.88)	\$ (1.95)

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

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PEREGRINE PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS
AS OF APRIL 30, 2017 AND 2016

	2017	2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 46,799,000	\$ 61,412,000
Trade and other receivables	7,742,000	2,859,000
Inventories	33,099,000	16,186,000
Prepaid expenses	1,460,000	1,351,000
Total current assets	89,100,000	81,808,000
PROPERTY AND EQUIPMENT:		
Leasehold improvements	20,098,000	19,610,000
Laboratory equipment	10,777,000	10,257,000
Furniture, fixtures, office equipment and software	4,499,000	4,045,000
	35,374,000	33,912,000
Less accumulated depreciation and amortization	(11,700,000)	(9,610,000)
Property and equipment, net	23,674,000	24,302,000
Restricted cash	1,150,000	600,000
Other assets	4,188,000	2,333,000
TOTAL ASSETS	\$ 118,112,000	\$ 109,043,000

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PEREGRINE PHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS
AS OF APRIL 30, 2017 AND 2016 (continued)

	2017	2016
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	\$ 5,779,000	\$ 8,429,000
Accrued clinical trial and related fees	4,558,000	7,594,000
Accrued payroll and related costs	6,084,000	5,821,000
Deferred revenue	28,500,000	10,030,000
Customer deposits	17,017,000	24,212,000
Other current liabilities	993,000	1,488,000
Total current liabilities	62,931,000	57,574,000
Deferred rent, less current portion	1,599,000	1,395,000
Commitments and contingencies		
STOCKHOLDERS' EQUITY ⁽¹⁾ :		
Preferred stock - \$.001 par value; authorized 5,000,000 shares; issued and outstanding - 1,647,760 and 1,577,440, respectively	2,000	2,000
Common stock - \$.001 par value; authorized 500,000,000 shares; issued and outstanding - 44,014,040 and 33,847,213, respectively	44,000	34,000
Additional paid-in-capital	590,971,000	559,314,000
Accumulated deficit	(537,435,000)	(509,276,000)
Total stockholders' equity	53,582,000	50,074,000
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 118,112,000	\$ 109,043,000

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

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