
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 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): November 7, 2018

Portola Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-35935
(Commission
File Number)

20-0216859
(IRS Employer
Identification No.)

270 E. Grand Avenue
South San Francisco, California
(Address of principal executive offices)

94080
(Zip Code)

Registrant's telephone number, including area code: (650) 246-7300

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

- 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 240.14d-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 November 7, 2018, Portola Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2018. The full text of the press release issued in connection with the announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Form 8-K and the Exhibit attached hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Number</u>	<u>Description of Document</u>
99.1	Press release entitled “Portola Pharmaceuticals Reports Third Quarter 2018 Financial Results and Provides Corporate Update” dated November 7, 2018.

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.

Portola Pharmaceuticals, Inc.

Dated: November 7, 2018

By: /s/ Mike Ouimette
Mike Ouimette
Executive Director, Corporate Counsel and Assistant
Corporate Secretary



Portola Pharmaceuticals Reports Third Quarter 2018 Financial Results and Provides Corporate Update

*– Third Quarter Andexxa Product Revenues of \$7.7 Million –
– Company Improves Financial Expectations for 2018 Operating Expenses –
– Conference Call Today at 4:30 p.m. ET –*

South San Francisco, Calif. (November 7, 2018) – Portola Pharmaceuticals, Inc.[®] (Nasdaq: PTLA) today reported financial results for the three months ended September 30, 2018 and provided a corporate update.

“I am excited to join Portola at such a pivotal moment in the Company’s history. Having just completed my first month in role, I am very encouraged by the progress and momentum we’ve achieved since prioritizing Andexxa, including our preparations for the potential approval of Generation 2 supply in the United States and in Europe,” said Scott Garland, Portola’s president and chief executive officer. “The early feedback from our first full quarter of sales gives us confidence in the significant long-term potential for Andexxa, and we are now implementing our new focused strategy for Bevyxxa. I am also excited about the potential for cerdulatinib, which recently received Orphan Drug Designation. We have a number of critical milestones ahead that I expect we will achieve and we look forward to delivering our life-saving medications to more patients, and driving sustainable growth and value for shareholders.”

Third Quarter 2018 Financial Results

Total revenue for the third quarter of 2018 was \$14.2 million, compared with \$3.8 million for the third quarter of 2017. This includes \$7.7 million in product revenue for our first full quarter of Andexxa sales and \$7.0 million in collaboration and license revenues. Bevyxxa product orders remained relatively flat in the third quarter, during which we recognized a net product loss for Bevyxxa of \$552 thousand. This adjustment was primarily related to potential returns of initial launch quantities provided to wholesalers.

Total operating expenses for the third quarter of 2018 were \$83.3 million, compared with \$84.3 million for the same period in 2017. Total operating expenses for the third quarter of 2018 included \$11.4 million in stock-based compensation expense, compared with \$10.1 million for the same period in 2017.

Research and development expenses were \$40.2 million for the third quarter of 2018, compared with \$55.3 million for the third quarter of 2017. The decrease is driven primarily by the timing of manufacturing costs for Andexxa Generation 2 campaigns. Approximately \$12 million, or 30 percent, of R&D expense for the quarter and \$75 million, or 45 percent, for nine months year-to date of total R&D expense was related to Andexxa manufacturing.

Selling, general and administrative expenses for the third quarter of 2018 were \$38.8 million, compared with \$28.9 million for the same period in 2017, reflecting the investment in our field force and marketing for our product launches.

For the third quarter of 2018, Portola reported a net loss of \$71.3 million, or \$1.08 net loss per share, compared with a net loss of \$82.9 million, or \$1.41 net loss per share, for the same period in 2017.

Cash, cash equivalents and investments at September 30, 2018 totaled \$380.9 million, compared with \$534.2 million as of December 31, 2017.

2018 Annual Financial Guidance

For the fiscal year 2018, Portola is updating its guidance for GAAP operating expenses, which are now expected to be between \$355 million and \$365 million, a decrease from the prior guidance range of between \$390 million and \$430 million, both including stock-based compensation. The updated guidance reflects the Company's narrowed focus on a group of key hospitals for the Bevyxxa launch, as well as additional cost savings for the year.

Recent Achievements and Events

- Appointed industry veteran Scott Garland as president and chief executive officer.
- Submitted Prior Approval Supplement (PAS) to U.S. FDA for large-scale Generation 2 Andexxa manufacturing process; assigned a PDUFA date of December 31, 2018.
- Transitioned commercial focus to the ongoing Andexxa U.S. launch under the Early Supply Program.
- Secured New Technology Add-on Payment (NTAP) for Andexxa, which became effective as of October 1, 2018.
- Implemented new strategy for Bevyxxa U.S. launch focused on establishing 10 Centers of Excellence to provide a model for driving broader adoption.
- Received Orphan Drug Designation from the U.S. Food and Drug Administration for cerdulatinib for the treatment of peripheral T-cell lymphoma.
- Eight abstracts presented at the European Society of Cardiology (ESC) meeting.

Upcoming Milestones

- Anticipated broad launch of Andexxa in early 2019, upon FDA approval of Generation 2 supply.
- Committee for Medicinal Products for Human Use (CHMP) opinion on andexanet alfa, with potential for European approval of andexanet alfa in the first half of 2019.
- End-of-Phase 2 meeting and determination of regulatory path forward for cerdulatinib in Q1 2019.
- New interim Phase 2a study results for cerdulatinib to be presented in an oral session at the 60th American Society of Hematology (ASH) Annual Meeting. Also accepted for presentation: outcomes-based research on the burden of hospital readmissions for venous thromboembolism among patients with cancer (oral) and two poster presentations on andexanet alfa.

Conference Call Details

Portola will host a conference call today, Wednesday, November 7, 2018, at 4:30 p.m. ET, during which time management will discuss the third quarter 2018 financial results, updates on the U.S. launches of Andexxa and Bevyxxa, and other matters. The live call can be accessed by phone by dialing (844) 452-6828 from the U.S. and Canada or 1 (765) 507-2588 internationally and using the passcode 3387315. The webcast can be accessed live on the Investor Relations section of the Company's website at <http://investors.portola.com>. It will be archived for 30 days following the call.

Unaudited Condensed Consolidated Statements of Operations

(In thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues:				
Product revenue, net	\$ 7,176	\$ —	\$ 10,047	\$ —
Collaboration and license revenue	7,001	3,828	14,785	12,743
Total revenues	14,177	3,828	24,832	12,743
Operating expenses:				
Cost of Sales	4,292	155	5,680	155
Research and development	40,237	55,273	166,744	135,210
Selling, general and administrative	38,792	28,856	110,547	64,206
Total operating expenses	83,321	84,284	282,971	199,571
Loss from operations	(69,144)	(80,456)	(258,139)	(186,828)
Interest and other income, net	3,924	663	9,123	952
Interest expense	(5,957)	(3,148)	(12,642)	(8,243)
Net loss	(71,177)	(82,941)	(261,658)	(194,119)
Net (income) loss attributable to noncontrolling interest (SRX Cardio)	(126)	5	(17)	(190)
Net loss attributable to Portola	\$ (71,303)	\$ (82,936)	\$ (261,675)	\$ (194,309)
Net loss per share attributable to Portola common stockholders:				
Basic and diluted	\$ (1.08)	\$ (1.41)	\$ (3.97)	\$ (3.38)
Shares used to compute net loss per share attributable to Portola common stockholders:				
Basic and diluted	66,165,104	58,940,764	65,855,672	57,569,593

Unaudited Condensed Consolidated Balance Sheet Data
(In thousands)

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
	(Unaudited)	
Cash, cash equivalents and investments	\$ 380,865	\$ 534,233
Prepaid research and development	963	734
Prepaid manufacturing	4,071	2,333
Trade and other receivables, net	7,150	3,750
Unbilled - collaboration and license revenue	9,872	—
Total current assets	403,692	477,923
Property and equipment, net	4,921	5,217
Intangible assets	7,423	7,851
Prepaid and other long-term assets	20,788	9,609
Total assets	447,705	571,676
Accounts payable	15,163	9,304
Accrued research and development	16,675	44,973
Accrued compensation and other liabilities	17,490	15,078
Deferred revenue (current portion and long-term)	7,443	29,967
Current portion of notes payable and long term debt	9,395	—
Total current liabilities	61,081	80,524
Notes payable, less current portion	49,074	50,565
Long term debt, less current portion	152,675	54,251
Long term obligation to collaborator, less current portion	7,204	8,000
Total liabilities	280,777	222,183
Total Portola stockholders' equity	164,424	346,866
Noncontrolling interest (SRX Cardio)	2,504	2,627
Total stockholders' equity	166,928	349,493
Total liabilities and stockholders' equity	447,705	571,676

About Portola Pharmaceuticals, Inc.

Portola Pharmaceuticals is a commercial-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics that could significantly advance the fields of thrombosis and other hematologic diseases. The Company's two FDA-approved medicines are Andexxa® [coagulation factor Xa (recombinant), inactivated-zhzo], the first and only antidote for patients treated with rivaroxaban and apixaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding, and Bevyxxa® (betrixaban), the first and only oral, once-daily Factor Xa inhibitor for the prevention of VTE in adult patients hospitalized for an acute medical illness. The company also is advancing cerdulatinib, a Syk/JAK inhibitor for the treatment of hematologic cancers.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, the statements under the caption "Upcoming Milestones," and those regarding 2018 financial guidance and potential regulatory approvals. Risks that contribute to the uncertain nature of the forward-looking statements include: the risk that physicians, patients and payers may not see the benefits of utilizing Andexxa or Bevyxxa for the indications which they are approved; our ability to continue to manufacture our products and to expand approved manufacturing facilities; the possibility of unfavorable results from additional clinical trials involving Andexxa; the risk that the EMA may not approve Andexxa in the currently anticipated timelines or at all, and that any marketing approvals or reimbursement limitations may have significant limitations on its use; the risk that Portola may not obtain additional regulatory approvals necessary to expand approved indications for Andexxa; our expectation that we will incur losses for the foreseeable future and will need additional funds to finance our operations; the accuracy of our estimates regarding expenses and capital requirements; our ability to successfully build a hospital-based sales force and commercial infrastructure; our ability to obtain and maintain intellectual property protection for our product candidates; and our ability to retain key scientific or management personnel. These and other risks and uncertainties are described more fully in our most recent filings with the Securities and Exchange Commission, including our most recent quarterly report on Form 10-Q. All forward-looking statements contained in this press release speak only as of the date on which they were made. We undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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Investor Contact:

Cara Miller
Portola Pharmaceuticals
ir@portola.com

Media Contact:

Patrick Ryan
Pure Communications
pryan@purecommunications.com