
**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): May 8, 2019

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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	PTLA	The Nasdaq Global Select Market

Item 2.02 Results of Operations and Financial Condition

On May 8, 2019, Portola Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2019. 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 First Quarter 2019 Financial Results and Provides Corporate Update” dated May 8, 2019.

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.

Dated: May 8, 2019

Portola Pharmaceuticals, Inc.

By: /s/ Mike Ouimette

Mike Ouimette

Executive Director, Corporate Counsel and Assistant Corporate Secretary



**Portola Pharmaceuticals Reports First Quarter 2019 Financial Results
and Provides Corporate Update**

*– First Quarter Revenues of \$22.2 Million;
Andexxa[®] Product Revenues Grow 45% to \$20.3 Million –*

*– European Commission Approval of Ondexxya[®]; Staged Commercial Launch Planned in
Second Half of 2019 –*

– Conference Call Today at 5:30 a.m. PT / 8:30 a.m. ET –

South San Francisco, Calif., (May 8, 2019) – Portola Pharmaceuticals, Inc. [®] (Nasdaq: PTLA) today reported financial results for the three months ended March 31, 2019 and provided a corporate update.

“Our first quarter results continue to reflect strong demand for Andexxa, as well as focused execution on our commercial launch. The full commercial U.S. launch of Andexxa is off to a great start, and with approval of Ondexxya in Europe, we now have another long-term growth catalyst and the ability to impact thousands of additional patient lives,” said Scott Garland, Portola’s president and chief executive officer. “Additionally, we continue to make progress with cerdulatinib and look forward to further defining the safety and efficacy profile, along with that of Andexxa, in a number of scientific presentations anticipated in Q2.”

Quarter Ending March 31, 2019

- Total revenues for the first quarter of 2019 were \$22.2 million, compared with \$6.6 million for the first quarter of 2018. This includes \$20.3 million in net product revenues from Andexxa sales, \$77 thousand in revenues from Bevyxxa[®] sales and \$1.8 million in collaboration and license revenues. Please see the tables at the end of this press release for a detailed breakdown of revenues.
- Net loss attributable to Portola, according to generally accepted accounting principles in the U.S. (GAAP), was \$78.2 million for the first quarter of 2019, or \$1.17 net loss per share, compared with a net loss of \$84.2 million, or \$1.28 net loss per share, for the same period in 2018. This includes the effect of two charges taken in the first quarter related to the FDA approval for the Company’s Gen 2 manufacturing process. The first is a \$5.8 million charge associated with the valuation of the Company equity that will be issued to Lonza, our Andexxa Gen 2 manufacturer (“manufacturing site charge”), and the second is a \$3.9 million charge associated with the Andexxa Gen 1 product as hospitals transition to the Gen 2 product (“Gen 1 supply charge”).
- Non-GAAP net loss for the first quarter of 2019 was \$68.4 million, or a non-GAAP basic and diluted loss per share of \$1.02. Non-GAAP net loss and net loss per share have been adjusted to remove the manufacturing site charge and the Gen 1 supply charge. Please see the reconciliation of GAAP to non-GAAP financial measures at the end of this release for more details.

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- Cash, cash equivalents and investments at March 31, 2019 totaled \$322.8 million, compared with \$317.0 million as of December 31, 2018. In March, the Company entered into a \$125 million loan agreement and received an initial tranche of \$62.5 million, with the balance available at Portola's option in the third quarter, subject to certain conditions, extending our cash runway to the end of 2020.
 - Total operating expenses for the first quarter of 2019 were \$95.8 million, compared with \$91.9 million for the same period in 2018. The increase was driven by the timing of launch activities in the U.S., the build-out of the Company's field force and launch preparations in Europe.
 - Non-GAAP total operating expenses, which excludes the two charges outlined above, were \$86.0 million for the first quarter of 2019. Please see the reconciliation of GAAP to non-GAAP financial measures table at the end of this release for more details.
 - Stock-based compensation expense for the first quarter of 2019 was \$17.9 million, compared with \$11.0 million for the same period in 2018. This year-over-year increase was driven primarily by the equity issued for the manufacturing site charge.
 - Cost of Sales (COS) for the first quarter of 2019 were \$7.2 million, compared to \$336 thousand for the same period in 2018. The increase was driven by the launch of Andexxa and the Gen 1 supply charge.
 - Research and development (R&D) expenses were \$35.6 million for the first quarter of 2019, compared with \$60.1 million for the first quarter of 2018. The decrease was driven primarily by the manufacturing costs for Andexxa Gen 2 being capitalized and no longer flowing through R&D.
 - Selling, general and administrative (SG&A) expenses for the first quarter of 2019 were \$53.0 million, compared with \$31.5 million for the same period in 2018. The increase was driven by the expansion of the Company's field force, commercial activities to support the launch of Andexxa and launch preparations in Europe.

Recent Achievements and Events

- Received European Commission approval of Ondexxya and hired Head of Europe to build a team to support planned commercial activity.
- Received C-code from The Centers for Medicare & Medicaid Services, allowing hospitals an additional reimbursement pathway for Andexxa.
- Submitted additional data to the U.S. Food and Drug Administration on the proposed dose for cerdulatinib.
- Announced the retirements of Portola co-founder Charles Homey, M.D. from the Board of Directors, and John Cumutte, M.D., Ph.D., Executive Vice President of Research and Development.

Upcoming Milestones

- Staged launch of Ondexxya in a select group of high-potential European countries where Factor Xa use is among the highest.
- Present new data on:
 - The impact of Andexxa on patients with an intracranial hemorrhage at the European Stroke Organization Conference in Milan in May.
 - The question of whether PCCs have clinical activity in the reversal of direct FXa inhibitors at the International Society of Thrombosis and Hematology meeting in Melbourne.
 - The safety and efficacy of cerdulatinib in relapsed/refractory follicular lymphoma, either alone or in combination with rituximab.
- Initiate discussions with the FDA on a number of potential label expansion opportunities including the addition of the ANNEXA-4 efficacy data, the inclusion of edoxaban and enoxaparin, and the potential initiation of a study in urgent surgery.

Conference Call Details

Portola will host a conference call today, Wednesday, May 8, 2019, at 8:30 a.m. ET, during which time management will discuss the first quarter 2019 financial results, updates on the U.S. launch of Andexxa, launch preparations in Europe 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 1684446. 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.

Use of Non-GAAP Financial Measures

This press release and the reconciliation table included herein include non-GAAP net loss, non-GAAP basic and diluted loss per share and non-GAAP operating expenses. The Company believes the presentation of non-GAAP financial measures provides useful information to management and investors regarding the company's financial condition and results of operations. When viewed in conjunction with GAAP financial measures, investors are provided with a more meaningful understanding of the Company's ongoing operating performance and are better able to compare the Company's performance between periods. In addition, these non-GAAP financial measures are among those that the Company uses as a basis for evaluating performance, allocating resources and planning and forecasting future periods. Non-GAAP financial measures are not intended to be considered in isolation or as a substitute for GAAP financial measures. A reconciliation of GAAP to non-GAAP financial measures is provided in the accompanying table entitled "Reconciliation of GAAP to Non-GAAP Financial Measures."

Reconciliation of GAAP to Non-GAAP Financial Measures

Three Months Ended March 31, 2019

(In thousands, except per share data)	GAAP Amount	Non-GAAP Adjustments	Non-GAAP Amount
Product revenue, net	\$ 20,362	—	\$ 20,362
Collaboration and license revenue	1,807	—	1,807
Total revenues	22,169	—	22,169
Cost of sales	7,150	(3,949)	3,201
Research and development	35,584	(5,824)	29,760
Selling, general and administrative	53,034	—	53,034
Total operating expenses	95,768	(9,773)	85,995
Net loss attributable to Portola	\$ (78,156)	9,773	\$ (68,383)
Net loss per share (basic/diluted)	\$ (1.17)	\$ 0.15	\$ (1.02)
Shares used to compute loss per share	<u>67,070,168</u>		<u>67,070,168</u>

Notes: Non-GAAP adjustments consist of: (1) A \$5.8 million charge associated with the valuation of the Company equity that was issued in 1Q'19 to Lonza, our Andexxa Gen 2 manufacturer, and (2) a \$3.9 million charge associated with our Andexxa Gen 1 product as we transition hospitals to Gen 2 product, following approval on December 31, 2018.

Unaudited Condensed Consolidated Statements of Operations

(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2019	2018
Revenues:		
Product revenue, net	\$ 20,362	\$ 606
Collaboration and license revenue	1,807	6,038
Total revenues	<u>22,169</u>	<u>6,644</u>
Operating expenses:		
Cost of Sales	7,150	336
Research and development	35,584	60,067
Selling, general and administrative	53,034	31,541
Total operating expenses	<u>95,768</u>	<u>91,944</u>
Loss from operations	(73,599)	(85,300)
Interest and other expense, net	1,984	3,371
Interest expense	(6,481)	(2,581)
Net loss	(78,096)	(84,510)
Net (income) loss attributable to noncontrolling interest	(60)	332
Net loss attributable to Portola	<u>\$ (78,156)</u>	<u>\$ (84,178)</u>
Net loss per share attributable to Portola common stockholders:		
Basic and diluted	<u>\$ (1.17)</u>	<u>\$ (1.28)</u>
Shares used to compute net loss per share attributable to Portola common stockholders:		
Basic and diluted	<u>67,070,168</u>	<u>65,509,945</u>

Unaudited Condensed Consolidated Balance Sheet Data

(In thousands)

	March 31, 2019	December 31, 2018
	(Unaudited)	
Cash, cash equivalents and investments	\$ 322,841	\$ 316,964
Trade and other receivables, net	11,787	5,849
Unbilled - collaboration and license revenue	6,317	9,880
Inventories	2,672	7,873
Property and equipment, net	5,032	5,236
Intangible assets	7,137	7,279
Other assets	44,596	33,338
Total assets	<u>\$ 400,382</u>	<u>\$ 386,419</u>
Current liabilities	\$ 73,828	\$ 69,005
Long-term liabilities	275,904	226,847
Total stockholders' equity	<u>50,650</u>	<u>90,567</u>
Total liabilities and stockholders' equity	<u>\$ 400,382</u>	<u>\$ 386,419</u>

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 or 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: statements regarding the anticipated launch timing, strategy and revenues for Ondexxa in Europe and potential treatment benefits of our products and product candidates; our plans to present new data and continue development of our products and product candidates; our expectation that our cash runway will extend to the end of 2020. 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 for the indications which it is 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; our ability to establish commercial operations in the EU and generate product revenue within projected timelines and budget; 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 annual report on Form 10-K. 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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