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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
**Pursuant to Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): December 11, 2018**

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**Portola Pharmaceuticals, Inc.**  
(Exact name of registrant as specified in its charter)

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**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**

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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.

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**Item 8.01 Other Events.**

On December 11, 2018, Portola Pharmaceuticals, Inc., issued a press release entitled “CHMP Extends Review Period for Portola Pharmaceuticals’ Ondexxya™ (andexanet alfa).” A copy of the press release is attached as Exhibit 99.1 to this report.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Number</u>	<u>Description of Document</u>
99.1	<a href="#">Press Release entitled “CHMP Extends Review Period for Portola Pharmaceuticals’ Ondexxya™ (andexanet alfa)”</a>

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**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: December 11, 2018

**Portola Pharmaceuticals, Inc.**

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



**CHMP Extends Review Period for Portola Pharmaceuticals’  
Ondexxya™ (andexanet alfa)**

**South San Francisco, Calif. (December 11, 2018)** – Portola Pharmaceuticals, Inc.® (Nasdaq: PTLA) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has extended the review period for the Company’s marketing authorization application (MAA) for Ondexxya™ (andexanet alfa), and cancelled the Oral Explanation scheduled for Wednesday, December 12, 2018. An opinion is now expected by February 28, 2019.

The CHMP informed Portola yesterday that it will provide a list of outstanding questions related to the data package the Company submitted for Ondexxya last quarter, which will require additional responses from the Company. The preliminary timetable provided to the Company by the CHMP sets a deadline of January 29, 2019 for responses to the questions followed by a 30-day assessment period for the CHMP to review the Company’s responses.

Ondexxya is under review for the reversal of the anticoagulant effects of the Factor Xa inhibitors apixaban and rivaroxaban in patients experiencing uncontrolled or life-threatening bleeding.

“We will work diligently to address the Committee’s questions as they review and further consider the data package supporting the MAA,” said Scott Garland, Portola’s president and chief executive officer. “We look forward to continuing the dialogue as we progress toward a formal opinion and potential European approval early next year.”

Andexanet alfa was approved by the U.S. Food and Drug Administration in May 2018 and is marketed by Portola in the U.S. under the trade name Andexxa® [coagulation factor Xa (recombinant), inactivated-zhzo].

**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

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include, but are not limited to, statements regarding the regulatory pathway for potential approval of Ondexxya in the EU. Risks that contribute to the uncertain nature of the forward-looking statements include: the risk that the EMA may not approve Ondexxya 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 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 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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