PORTOLA PHARMACEUTICALS INC
Form 8-K
December 15, 2016

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): December 9, 2016

Portola Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-35935**	**20-0216859**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

270 E. Grand Avenue

South San Francisco, California	**94080**
(Address of principal executive offices)	**(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))

Item 1.01 Entry into a Material Definitive Agreement.

On December 9, 2016, Portola Pharmaceuticals, Inc. (the **Company**) entered into an Amended and Restated Commercial Supply (Manufacturing Services) Agreement (the **Agreement**) with CMC ICOS Biologics, Inc. (**CMC**), pursuant to which the Company will purchase from CMC commercial supply of Andexanet alfa and CMC will provide other services supporting the Company s regulatory applications in the United States and European Union. The Agreement amends and restates the Commercial Supply (Manufacturing Services) Agreement between the parties dated July 1, 2014 (the **Original Agreement**).

Under the Agreement, the Company is required to purchase a fixed number of batches of Andexanet alfa from CMC from 2017 through 2018 at a set batch price. The batches will be manufactured on the 2,500 liter manufacturing line referred to as Line A/B and CMC and the Company have agreed to discontinue manufacturing on the 6x2,000 liter manufacturing line referred to as Line C. CMC will also perform the services necessary to provide the Company with the deliverables required by the complete response letter from FDA dated August 17, 2016 (the **CRL**) in order for the Company to resubmit its BLA for Andexanet alfa and to provide certain support for the Company s Marketing Authorization Application for Andexanet alfa with the European Medicines Agency.

Pursuant to the terms of the agreement, the Company received a $33.7 million credit, which may be applied to either satisfy or partially offset, pursuant to the terms of the Agreement, specified amounts owed to CMC for manufacturing fees, successful delivery of the CRL deliverables and other specific deliverables associated with improving the manufacturing process, other services and development work provided by CMC, outstanding invoices and a milestone success fee upon FDA approval of Andexanet alfa.

The Agreement includes a general release of claims by both parties relating to manufacturing services provided to date (the **Release**). The term of the Agreement is two years and may be earlier terminated by either party for the other party s uncured material breach or insolvency. The Company may terminate the Agreement unilaterally if the Company s applications for regulatory approval for Andexanet alfa in the United States and European Union are rejected, for any other safety, efficacy or commercial reasons that lead to the discontinuation, reduction in market demand or commercial infeasibility of Andexanet alfa. The Company or CMC may also terminate the Agreement prior to February 15, 2017 if certain contingencies have not been removed by that date, in which case the Release would also be terminated and the parties would be returned to their respective positions prior to the signing of the Agreement.

The foregoing is only a summary of the material terms of the Agreement, does not purport to be a complete description of the rights and obligations of the parties thereunder and is qualified in its entirety by reference to the Agreement that will be filed as an exhibit to the Company s Annual Report on Form 10-K for the fiscal year ended December 31, 2016.

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: December 15, 2016

By: /s/ Mardi C. Dier
Mardi C. Dier
Executive Vice President and Chief Financial Officer