

Prothena Corp plc
Form 8-K
November 09, 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): November 9, 2016

PROTHENA CORPORATION PUBLIC LIMITED COMPANY
(Exact Name of Registrant as Specified in its Charter)

Ireland	001-35676	98-1111119
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Adelphi Plaza
Upper George's Street, Dún Laoghaire
Co. Dublin, A96 T927
Ireland

(Address of principal executive offices including Zip Code)
Registrant's telephone number, including area code: 011-353-1-236-2500

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 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 1.01 Entry into a Material Definitive Agreement.

On November 9, 2016, Prothena Therapeutics Limited (“Prothena”), a wholly owned subsidiary of Prothena Corporation plc (together with its subsidiaries, the “Company”), entered into a Commercial Supply Contract (the “Supply Contract”) with Rentschler Biotechnologie GmbH (“Rentschler”), under which Rentschler agreed to manufacture and supply bulk drug substance of NEOD001, Prothena’s monoclonal antibody for the potential treatment of AL amyloidosis, to Prothena for worldwide commercial sale purposes if Prothena applies for and receives regulatory approval to market NEOD001 (the “Product”).

Under a Master Development Services Agreement dated August 10, 2015 between Prothena and Rentschler, Prothena previously initiated a transfer of manufacturing technology to Rentschler to enable Rentschler to develop the capability to manufacture NEOD001 for Prothena for commercial purposes (the “Technology Transfer”). The Technology Transfer to Rentschler, from Boehringer Ingelheim Biopharmaceuticals GmbH (“BI”), Prothena’s current third-party manufacturer of NEOD001 for clinical development, is on-going.

Under the Supply Contract, Rentschler is obligated to have the capacity, following successful completion of the Technology Transfer and prior to receipt of regulatory approval to market the Product, to produce a specified quantity of the Product. Prothena has a minimum purchase obligation of a specified quantity of the Product, but beyond that quantity Prothena may source bulk drug substance of NEOD001 from other manufacturers, and Rentschler is obligated to cooperate with Prothena in any such efforts, including by performing certain technology transfers.

Prothena agreed to place any binding purchase orders with Rentschler with certain specified lead times. Prothena will be obligated to pay cancellation fees for any cancelled binding purchase order, unless Rentschler is able to utilize for another customer the manufacturing slots reserved for such cancelled order (which Rentschler is obligated to use commercially reasonable efforts to do).

The Supply Contract has an initial term of seven years, with an automatic two-year extension unless either party provides at least eighteen months’ prior written notice to the other party of its intention to terminate at the end of the initial term or during the renewal term. However, Prothena may give written notice of termination of the Supply Contract if the Technology Transfer from BI to Rentschler has not been completed by June 30, 2017 (unless that failure to complete the Technology Transfer is due to certain actions or inactions by Prothena). In addition, either party may terminate the Supply Contract with prior written notice for an uncured material breach of the Supply Contract by the other party. Following a termination of the Supply Contract, Rentschler is obligated to transfer the then-current manufacturing technology to Prothena’s designated manufacturer.

The Supply Contract includes standard and customary provisions regarding, among other things, compliance with laws and regulations, confidentiality, intellectual property, representations and warranties, liability, indemnification, insurance, termination, remedies, dispute resolution and assignability.

The foregoing description of the material terms of the Supply Contract does not purport to be complete and is qualified in its entirety by reference to the Supply Contract, which the Company intends to file as an exhibit to its Annual Report on Form 10-K for the year ending December 31, 2016. The Company intends to seek confidential treatment for certain portions of the Supply Contract pursuant to a Confidential Treatment Request to be submitted to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 9, 2016 PROTHENA CORPORATION
PLC

By: /s/ Tran B. Nguyen
Name: Tran B. Nguyen
Title: Chief Financial Officer