Prothena Corp plc
Form 8-K
December 11, 2013

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 11, 2013

Prothena Corporation plc
(Exact Name of Registrant as Specified in its Charter)

Ireland
(State or Other Jurisdiction of Incorporation)

001-35676	98-1111119
(Commission File Number)	(IRS Employer Identification No.)

650 Gateway Boulevard
South San Francisco, California 94080
(Address of Principal Executive Offices, including Zip Code)
Registrant's telephone number, including area code: (650) 837-8550

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):

- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- o 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 11, 2013, Neotope Biosciences Limited ("Neotope") and Prothena Biosciences Inc ("PBI", and together with Neotope, "Prothena"), each a wholly owned subsidiary of Prothena Corporation plc, entered into a License, Development, and Commercialization Agreement (the "License Agreement") with F. Hoffmann-La Roche Ltd. and Hoffmann-La Roche Inc. (together, "Roche") to develop and commercialize certain antibodies that target alpha-synuclein, including PRX002, Prothena's monoclonal antibody for the treatment of Parkinson's disease (collectively, the "Licensed Products"). The effectiveness of the License Agreement is subject to the completion of customary regulatory clearances, including expiration of the applicable Hart-Scott-Rodino ("HSR") waiting period.

Upon the effectiveness of the License Agreement, Prothena will grant to Roche an exclusive, worldwide license to develop, make, have made, use, sell, offer to sell, import, and export the Licensed Products. Prothena will retain certain rights to conduct development of the Licensed Products and an option to co-promote PRX002. Thereafter, during the term of the License Agreement, Prothena and Roche will work exclusively with each other to research and develop antibody products targeting alpha-synuclein. Roche will provide funding for a research collaboration between the parties focused on optimizing early stage antibodies targeting alpha-synuclein, potentially including incorporation of Roche's proprietary Brain Shuttle™ technology to increase delivery of therapeutic antibodies to the brain.

After the filing of the investigational new drug application with the U.S. Food and Drug Administration for PRX002 by Prothena, Roche will be primarily responsible for developing, obtaining and maintaining regulatory approval for, and commercializing the Licensed Products. Roche will also become responsible for the clinical and commercial manufacture and supply of the Licensed Products within a defined time period following the effective date of the License Agreement.

The License Agreement provides that Roche will pay Prothena an upfront payment and a near-term clinical milestone payment totaling $45.0 million. For PRX002, Roche is also obligated to pay:

- up to $380.0 million upon the achievement of development, regulatory and first commercial sale milestones;
- up to an additional $175.0 million in ex-U.S. commercial sales milestones; and
- tiered, high single-digit to high double-digit royalties in the teens on ex-U.S. annual net sales, subject to certain adjustments.

In the United States, the parties will share all development and commercialization costs, as well as profits, all of which will be allocated 70% to Roche and 30% to Prothena, for PRX002 in the Parkinson's disease indication, as well as any other Licensed Products and/or indications for which Prothena opts in to participate in co-development and co-funding. Prothena may opt out of the co-development and cost and profit sharing on any co-developed Licensed Products and instead receive U.S. commercial sales milestones totaling up to $155.0 million and tiered, single-digit to high double-digit royalties in the teens based on U.S. annual net sales, subject to certain adjustments, with respect to the applicable Licensed Product. In addition, Prothena has an option under the License Agreement to co-promote PRX002 in the United States in the Parkinson's disease indication. If Prothena exercises such option, it may also elect to co-promote additional Licensed Products in the United States approved for Parkinson's disease. Outside the United States, Roche will have responsibility for developing and commercializing the Licensed Products.

The License Agreement continues on a country-by-country basis until the expiration of all payment obligations under the License Agreement. The License Agreement may also be terminated (i) by Roche at will after the first anniversary of the effective date of the License Agreement, either in its entirety or on a Licensed Product-by-Licensed Product basis, upon 90 days' prior written notice to Prothena prior to first commercial sale and 180 days' prior written notice to Prothena after first commercial sale, (ii) by either party, either in its entirety or on a Licensed Product-by-Licensed Product or region-by-region basis, upon written notice in connection with a material breach uncured 90 days after

initial written notice, and (iii) by either party, in its entirety, upon insolvency of the other party. The License Agreement may be terminated by either party on a patent-by-patent and country-by-country basis if the other party challenges a given patent in a given country. Prothena's rights to co-develop Licensed Products under the License

Agreement will terminate if Prothena commences certain studies for certain types of competitive products. Prothena's rights to co-promote Licensed Products under the License Agreement will terminate if Prothena commences a Phase 3 study for such competitive products.

The License Agreement cannot be assigned by either party without the prior written consent of the other party, except to an affiliate of such party or in the event of a merger or acquisition of such party, subject to certain conditions. The License Agreement also includes customary provisions regarding, among other things, confidentiality, intellectual property ownership, patent prosecution, enforcement and defense, representations and warranties, indemnification, insurance, and arbitration and dispute resolution.

The foregoing description of the terms of the License Agreement does not purport to be a complete description and is qualified in its entirety by reference to the full text of the License Agreement, which Prothena intends to file as an exhibit to its Annual Report on Form 10-K for the year ending December 31, 2013.

Item 7.01 Regulation FD

On December 11, 2013, Prothena issued a press release announcing the License Agreement with Roche, a copy of which is furnished as Exhibit 99.1 to this Report and incorporated by reference.

The foregoing information in Item 7.01 of this Current Report on Form 8-K, together with the press release attached hereto as Exhibit 99.1, is being furnished pursuant to this Item 7.01 and 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, and it shall not be deemed incorporated by reference in any filing under the Securities Act or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to Item 7.01 of this Current Report on Form 8-K.

Forward-Looking Statements

The disclosures contained or incorporated by reference in Item 1.01 and Item 7.01 contain forward-looking statements regarding the License Agreement and the development of PRX002 and other Licensed Products, including the ability of Prothena and Roche to successfully research, develop and commercialize antibodies that target alpha-synuclein (including PRX002), the ability of Prothena and Roche to obtain regulatory approval to manufacture, market and sell Licensed Products, including PRX002, in or outside of the United States, the efficacy of Licensed Products, including PRX002, as a treatment for Parkinson's disease or other synucleinopathies, the ability for Prothena to achieve the milestones or receive royalties under the License Agreement in order to receive payments thereunder and the ability for the parties to satisfy all the conditions to effectiveness of the License Agreement, including HSR clearance. These forward-looking statements involve risks and uncertainties. Actual results could differ materially from those anticipated due to known and unknown risks, uncertainties and other factors, including but not limited to the risks and uncertainties described in Prothena's SEC filings, including the "Risk Factors" section of Prothena's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated December 11, 2013.

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.

Date: December 11, 2013

PROTHENA CORPORATION PLC

By: /s/ Dale B. Schenk
Name: Dale B. Schenk
Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release dated December 11, 2013.

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