PROTHENA CORP PLC

FORM 8-K
(Current report filing)

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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): March 20, 2018

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 Number)**

Adelphi Plaza
Upper George's Street, Dún Laoghaire
Co. Dublin, A96 T927, Ireland
011-353-1-236-2500
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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:

☐ 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 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. ☐

Item 1.01. Entry into a Material Definitive Agreement.

Collaboration Agreement

On March 20, 2018, Prothena Biosciences Limited ("Prothena"), a wholly owned subsidiary of Prothena Corporation plc (the "Company"), entered into a Master Collaboration Agreement (the "Collaboration Agreement") with Celgene Switzerland LLC ("Celgene"), pursuant to which Prothena granted to Celgene a right to elect in its sole discretion to exclusively license rights both in the U.S. (the "US Rights") and on a global basis (the "Global Rights"), with respect to the Company's programs to develop and commercialize antibodies targeting Tau, TDP-43 and an undisclosed target (the "Collaboration Targets"). For each such program, Celgene has an exclusive right to license clinical candidates in the U.S. at the investigational new drug (IND) filing and if exercised, would also have a right to expand the license to global rights at the completion of Phase 1. Following the exercise for global rights, Celgene would have decision making authority over all further global clinical development and commercialization.

Under the Collaboration Agreement, Celgene is obligated to pay Prothena an upfront payment of $100 million, as well as a further payment of approximately $50 million to subscribe for 1,174,536 of the Company's ordinary shares at a price of $42.57 per share, pursuant to a Share Subscription Agreement as described further below.

Celgene US and Global Rights and Licenses

On a program-by-program basis, following Prothena's filing of an investigational new drug (IND) application for any of our three collaboration programs to Celgene, Celgene may elect in its sole discretion to exercise its US Right to receive an exclusive license to develop and commercialize antibodies targeting the applicable Collaboration Target in the U.S. (the "US Rights"). If Celgene exercises the US Rights for a collaboration program, it is obligated to pay Prothena an exercise fee of approximately $80 million per program. Thereafter, Celgene would have decision making authority over development activities, and all regulatory, manufacturing and commercialization activities, for antibody products targeting the relevant Collaboration Target (the "Collaboration Products") in the U.S.

On a program-by-program basis, following completion of a Phase 1 clinical trial for a collaboration program for which Celgene has previously exercised its US Rights, Celgene may elect in its sole discretion to exercise its Global Rights with respect to such collaboration program to receive a worldwide, exclusive license to develop and commercialize antibodies targeting the applicable Collaboration Target (the "Global Rights"). If Celgene exercises its Global Rights, Celgene would be obligated to pay Prothena an additional exercise fee of $55 million for such collaboration program. The Global Rights would then replace the US Rights for that collaboration program, and Celgene would have decision making authority over developing, obtaining and maintaining regulatory approval for, manufacturing and commercializing the Collaboration Products worldwide.

After exercise of Global Rights for a collaboration program, Prothena is eligible to receive up to $562.5 million in regulatory and commercial milestones per program. For obtaining either US Rights or Global Rights for such collaboration program, Prothena will also be eligible to receive tiered royalties on net sales of Collaboration Products ranging from high single digit to high teen percentages, on a weighted average basis depending on the achieving of certain net sales thresholds. Such exercise fees, milestones and royalty payments are subject to certain reductions as specified in the Collaboration Agreement, the agreement for US Rights and the agreement for Global Rights.

Celgene will continue to pay royalties on a Collaboration Product-by- Collaboration Product and country-by-country basis, until the latest of (i) expiration of certain patents covering the Collaboration Product, (ii) expiration of all regulatory exclusivity for the Collaboration Product, and (iii) an agreed period of time after the first commercial sale of the Collaboration Product in the applicable country (the "Royalty Term").

Term and Termination

The research term under the Collaboration Agreement continues for a period of six (6) years, which Celgene may extend for up to two additional 12-month periods by paying an extension fee of $10 million per extension period. The term of Collaboration Agreement continues until the last to occur of the following: (i) expiration of the research term, (ii) expiration of all US Rights terms, and (iii) expiration of all Global Rights terms.

The term of any agreement for US Rights or Global Rights would continue on a Collaboration Product-by-Collaboration Product and country-by-country basis until the expiration of all Royalty Terms under such agreement.

The Collaboration Agreement may be terminated (i) by either party on a program-by-program basis if the other party remains in material breach of the Collaboration Agreement following a cure period to remedy the material breach, (ii) by Celgene at will on a program-by-program basis or in its entirety, (iii) by either party, in its entirety, upon insolvency of the other party, or (iv) by Prothena, in its entirety, if Celgene challenges a patent licensed by Prothena to Celgene under the Collaboration Agreement.

Share Subscription Agreement

Pursuant to the terms of the Collaboration Agreement, the Company entered into a Share Subscription Agreement (the "SSA") with Celgene on March 20, 2018, pursuant to which the Company has agreed to issue, and Celgene has agreed to subscribe for, 1,174,536 of the Company's ordinary shares (the "Shares") for an aggregate subscription price of approximately $50 million, pursuant to the terms and conditions thereof. The Company expects to close on the subscription of the Shares within 2 days following the effective date of the Collaboration Agreement.

Under the SSA, Celgene is subject to certain transfer and standstill restrictions, including a restriction on acquiring more than 9.9% of the Company's share capital for a specified period of time following the closing of the subscription of the Shares, or earlier upon announcement of the intent to consummate a change of control of the Company by the Company or a third party, or expiration or termination of the Collaboration Agreement. In additional, Celgene will be entitled to request the registration of the Shares on Form S-3ASR or Form S-3 following termination of the transfer restrictions if the Shares cannot be resold without restriction pursuant to Rule 144 promulgated under the Securities Act of 1933, as amended (the "Securities Act").

The foregoing description of the material terms of the Collaboration Agreement, US Rights, Global Rights and SSA does not purport to be a complete description and is qualified in its entirety by reference to the full text of the Collaboration Agreement and SSA, which the Company intends to file as exhibits to its Quarterly Report on Form 10-Q for the quarter ending March 31, 2018. The Company intends to seek confidential treatment for certain portions of the Collaboration Agreement 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 (the "Exchange Act").

Item 3.02. Unregistered Sales of Equity Securities.

The information contained in Item 1.01 above is incorporated by reference into this Item 3.02.

The issuance and delivery of Shares to Celgene pursuant to the SSA will be exempt from registration pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act and Regulation D promulgated under the Securities Act. Celgene represented that (a) it is an "accredited investor" within the meaning of Rule 501 of Regulation D promulgated under the Securities Act, (b) it is acquiring the Shares solely for investment with no present intention of distributing any of the Shares to any person in violation of applicable securities laws or pursuant to any arrangement or understanding with any other persons regarding the distribution of such Shares, except in compliance with the Securities Act or other applicable securities laws, and (c) it has been furnished with or has had full access to all the information, including the opportunity to discuss such information with our management, that it considers necessary or appropriate to make an informed investment decision with respect to the Shares. Appropriate legends will be affixed to the Shares. The Shares to be issued and subscribed for in connection with the SSA have not been registered under the Securities Act or any state securities laws and may not be offered or sold in the United States absent registration with the Securities and Exchange Commission or an applicable exemption from the registration requirements.

Item 7.01. Regulation FD Disclosure.

On March 20, 2018, the Company issued the press release attached as Exhibit 99.1 to this Current Report on Form 8-K, which is hereby furnished pursuant to Item 7.01 of Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information furnished pursuant to this Item 7.01, and including Exhibit 99.1 furnished herewith, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act nor shall such be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated March 20, 2018.

Forward-looking Statements

This Current Report on Form 8-K contains forward-looking statements by Prothena, and the webcast described in the press release attached hereto as Exhibit 99.1 will contain forward-looking statements by Prothena. These statements relate to, among other things, the potential for the collaboration with Celgene to apply our expertise, create significant value and opportunity for Prothena and accelerate our efforts to deliver a diversified pipeline of therapies; our potential disease modifying approaches to diseases in the neuroscience and orphan categories, including the potential of PRX002/RG7935 as a disease-modifying treatment for Parkinson's disease; our ability to generate antibodies that optimally target pathogenic forms of proteins for maximum efficacy, including the proteins that are the subject of the collaboration; potential future payments and royalties Prothena might receive under the collaboration; the potential to advance any of the programs that are the subject of the collaboration; the expected timing of announcing topline results from the Phase 2b study of NEOD001; the anticipated timing of the final event in the Phase 3 study of NEOD001; and the expected timing of advancing PRX004 into a Phase 1 clinical study. These statements are based on estimates, projections and assumptions that may prove not to be accurate, and 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, uncertainties and other factors described in the "Risk Factors" sections of Prothena's Annual Report on Form 10-K filed with the SEC on February 26, 2018 and Prothena's subsequent Quarterly Reports on Form 10-Q filed with the SEC. Prothena undertakes no obligation to update publicly any forward-looking statements contained in this report as a result of new information, future events or changes in Prothena's expectations.

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: March 20, 2018

PROTHENA CORPORATION PLC

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

Exhibit 99.1

Prothena Announces Global Neuroscience Research & Development Collaboration with Celgene for Novel Therapies for Patients with Neurodegenerative Diseases

- **Prothena to receive a $100 million upfront payment and a $50 million equity investment by Celgene, with potential license payments and regulatory and commercial milestones, plus additional royalties on net sales from licensed programs**
- **Collaboration focuses on preclinical programs targeting proteins implicated in several neurodegenerative diseases, including tau, TDP-43 and an undisclosed third target**
- **Prothena to host an investor conference call and webcast today at 5:00 PM ET**

DUBLIN, Ireland- March 20, 2018 – Prothena Corporation plc (NASDAQ:PRTA), a late-stage clinical biotechnology company focused on the discovery, development and commercialization of novel therapies in the neuroscience and orphan categories, today announced a global collaboration with Celgene Corporation (NASDAQ:CELG) through a subsidiary, to develop new therapies for a broad range of neurodegenerative diseases. The multi-year research and development collaboration is focused on three proteins implicated in the pathogenesis of several neurodegenerative diseases, including tau, TDP-43 and an undisclosed target. For each of the programs, Celgene has an exclusive right to license clinical candidates in the U.S. at the investigational new drug (IND) filing and if exercised, would also have a right to expand the license to global rights at the completion of Phase 1. Following the exercise of global rights, Celgene will be responsible for funding all further global clinical development and commercialization. Under the terms of the collaboration, Prothena will receive a $100 million upfront payment and a $50 million equity investment by Celgene, plus future potential exercise payments and regulatory and commercial milestones for each licensed program. Prothena will also receive additional royalties on net sales of any resulting marketed products.

“Prothena has a legacy of innovation in neuroscience and a team with a deep understanding of biological approaches that target protein misfolding disorders. Our collaboration leverages each company’s core expertise in protein homeostasis and protein clearance to target proteins that are the underlying cause of many neurodegenerative and orphan diseases. The programs we have chosen to collaborate on have the potential to provide foundational assets from which we can build new therapeutic approaches to these currently untreatable neurological disorders” said Richard Hargreaves, PhD, Corporate Vice President Neuroscience and Imaging for Celgene.

“We are excited to be working with Celgene, a leading global biopharmaceutical company with deep expertise in targeting critical biological pathways involved in protein homeostasis and an extensive track record of successfully bringing forward innovative new therapies based on this biology,” said Gene Kinney, PhD, President and Chief Executive Officer of Prothena. “As we

build our pipeline of novel therapies across the neuroscience and orphan disease categories, this collaboration provides Prothena the opportunity to work with a premier scientific partner and the resources and flexibility to advance these programs while continuing to expand our proprietary discovery activities and further supports our efforts to deliver a diversified pipeline of therapies to alter the course of devastating diseases."

Collaboration Agreement Overview

Prothena will receive an upfront payment and equity investment, and is eligible to receive exercise payments and regulatory and commercial milestones, plus additional royalties on net sales based on the following collaboration deal terms:

- Prothena will receive an upfront payment of $100 million
- Celgene will make a $50 million equity investment in Prothena by subscribing to approximately 1.2 million of Prothena's ordinary shares at $42.57 per share
- For programs reaching commercialization, Prothena will receive tiered royalties on net sales

The targets encompassed in this collaboration are implicated in the pathogenesis of several neurodegenerative diseases for which there are no current disease modifying therapies, including the following:

- **Tau,** a protein implicated in diseases including Alzheimer's disease (AD), progressive supranuclear palsy (PSP), frontotemporal dementia (FTD), chronic traumatic encephalopathy (CTE) and other tauopathies. Prothena has identified antibodies targeting novel epitopes on the tau protein with the ability to block misfolded tau from binding to cells and to inhibit cell-to-cell transmission, preventing downstream functional toxic effects.
- **TDP-43** , a protein implicated in diseases including amytrophic lateral sclerosis (ALS) and the most common subtype of FTD, behavioral variant FTD (bvFTD), a proportion of AD and other TDP-43 proteinopathies. Prothena has generated antibodies that target multiple epitopes on the TDP-43 protein and is using proprietary in vitro screening methodology to select those that may be the most potent and efficacious in inhibiting toxicity and cell-to-cell transmission of misfolded TDP-43 species.

Citi is acting as financial advisor to Prothena and Latham & Watkins LLP is acting as legal counsel to Prothena. Morgan Lewis is acting as legal counsel to Celgene.

Investor Conference Call and Webcast Details

Prothena management will host a conference call and webcast to discuss the collaboration today, March 20, at 5:00 PM ET. The conference call and webcast will be made available on the Company's website at www.prothena.com under the Investors tab in the Events and Presentations section. Following the conference call and webcast, a replay will be available on the Company's website for at least 90 days.

To access the conference call via dial-in, please dial (877) 887-5215 (U.S./Canada toll free) or (315) 625-3069 (international) five minutes prior to the start time and refer to conference ID number 8469456. A replay of the call will be available until March 27 via dial-in at (855) 859-2056 (U.S./Canada toll free) or (404) 537-3406 (international), Conference ID Number 8469456.

About Prothena

Prothena Corporation plc is a global, late-stage clinical biotechnology company establishing fully integrated research, development and commercial capabilities and focused on advancing new therapies in the neuroscience and orphan categories. Fueled by its deep scientific understanding built over decades of research in protein misfolding, Prothena seeks to fundamentally change the course of grave or currently untreatable diseases associated with this biology. Prothena's pipeline of antibody therapeutic candidates targets a number of indications including AL amyloidosis (NEOD001), Parkinson's disease and other related synucleinopathies (PRX002/RG7935) and ATTR amyloidosis (PRX004). The Company continues discovery of additional novel therapeutic approaches against targets such as tau, Aß (Amyloid beta) and ALECT2 where its deep scientific understanding of disease pathology can be leveraged. For more information, please visit the Company's website at www.prothena.com .

Forward-looking Statements by Prothena

This press release contains forward-looking statements by Prothena. These statements relate to, among other things, potential future payments and royalties we might receive under the collaboration with Celgene; our ability to advance a growing pipeline of novel therapies in the neuroscience and orphan disease categories; our ability to advance any of the programs that are the subject of the collaboration with Celgene; the potential of those programs to lead to new therapeutic approaches to currently untreatable neurological disorders; the potential targeting of novel epitopes on misfolded forms of tau protein and LECT2 protein; and the capabilities of our proprietary in vitro screening methodology for TDP-43. These statements are based on estimates, projections and assumptions that may prove not to be accurate, and 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, uncertainties and other factors described in the "Risk Factors" sections of Prothena's Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 26, 2018 and Prothena's subsequent Quarterly Reports on Form 10-Q filed with the SEC. Prothena undertakes no obligation to update publicly any forward-looking statements contained in this press release as a result of new information, future events or changes in Prothena's expectations.

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