# 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): May 6, 2020**

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# PROTHENA CORPORATION PUBLIC LIMITED COMPANY

**(Exact name of registrant as specified in its charter)**

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

**77 Sir John Rogerson's Quay, Block C**
**Grand Canal Docklands**
**Dublin 2, D02 T804, Ireland**

**(Address of principal executive offices, including Zip Code)**

**Registrant's telephone number, including area code: 011-353-1-236-2500**

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**(Former Name or Former Address, if Changed Since Last Report.)**

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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))

Securities registered pursuant to Section 12(b) of the Act:

| Title of Each Class | Trading Symbol | Name of Each Exchange on Which Registered |
|---|---|---|
| Ordinary Shares, par value $0.01 per share | PRTA | The Nasdaq Global Select Market |

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 o

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. o

**Item 2.02. Results of Operations and Financial Condition.**

*The information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto 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. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically incorporate by reference the information furnished pursuant to Item 2.02 (including Exhibit 99.1) of this Current Report.*

On May 6, 2020, Prothena Corporation plc issued a press release announcing its financial results for the first quarter ended March 31, 2020. A copy of that press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits**

(d) Exhibits.

| **Exhibit No.** | **Description** |
|---|---|
| 99.1 | Press Release dated May 6, 2020 |

**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: May 6, 2020

**PROTHENA CORPORATION PLC**

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

**Exhibit 99.1**

# Prothena Reports First Quarter 2020 Financial Results and Provides R&D Update and Updated Financial Guidance

- **Net cash used in operating and investing activities was $23.2 million in the first quarter; quarter-end cash and restricted cash position of $355.4 million provides funding to advance a broad pipeline**

DUBLIN, Ireland, May 6, 2020-- Prothena Corporation plc (NASDAQ:PRTA), a clinical-stage neuroscience company with expertise in protein misfolding, today reported financial results for the first quarter of 2020. In addition, the Company provided an update on its R&D programs and 2020 financial guidance.

“While the COVID-19 pandemic has brought significant challenges to people around the world and to our industry, Prothena has acted to protect the health of patients and our employees and the continuity of our programs,” said Gene Kinney, Ph.D., President and Chief Executive Officer of Prothena. “The situation is fluid and continues to evolve and as such we have identified potential disruptions and activated mitigation plans designed to advance our programs even under these challenging circumstances. Our team continues to manage critical activities, exhibiting extraordinary resilience, focus and commitment to advancing our pipeline of novel therapeutics for devastating diseases. We were fortunate that COVID-19 related disruptions began after patients in the Phase 2 prasinezumab study (PASADENA) and the Phase 1 PRX004 study had completed assessments that comprise the primary objective in each study.”

**First Quarter 2020 and Recent Developments**

- The Company continues to monitor the potential impacts of the COVID-19 pandemic to its business. Adaptations to the work environment have been implemented and the Company’s laboratories have remained productive. The known and potential impact to active clinical studies is described in more detail below. Prothena has drug supply for its ongoing studies and currently does not expect delays to its programs due to manufacturing or supply chain issues.
- As part of Roche’s first quarter earnings announcement, an update was provided on Part 1 of the Phase 2 PASADENA study of prasinezumab in patients with early Parkinson’s disease. As updated by Roche, the study did not meet the primary objective, but showed signals of efficacy. These signals were observed on multiple prespecified secondary and exploratory clinical endpoints. Roche has begun further clinical development planning activities and is evaluating the data from Part 1 of the PASADENA study to determine next steps. Based on ongoing evaluation of the data, including potential discussions with health authorities, a further update on prasinezumab is expected later this year.
- In a virtual oral presentation at the Advances in Alzheimer’s and Parkinson’s Therapies AAT-AD/PD Focus Meeting (AAT-AD/PD), Roche presented baseline data from the Phase 2 PASADENA study of prasinezumab in patients with early Parkinson's disease. The presentation, titled *A Phase 2 study to evaluate the safety and efficacy of prasinezumab in early Parkinson's disease (PASADENA): rationale, design and baseline data* is posted on www.prothena.com here. The presentation noted that the PASADENA study population can be considered representative of a wider Parkinson’s disease population, such as the one studied in the Parkinson's Progression Markers Initiative (PPMI) and is therefore suitable for testing the potential beneficial effect of drugs acting on disease progression, such as prasinezumab.

- The Company appointed Brandon Smith as Chief Business Officer to lead Prothena's business development initiatives, portfolio strategic planning and alliance management activities. Mr. Smith has extensive corporate, business development and operational expertise, and has held a number of executive roles at biotechnology companies.

**Research and Development Updates and Upcoming Milestones**

**Prasinezumab (PRX002/RG7935**), a potential treatment for Parkinson's disease, is a monoclonal antibody designed to target alpha-synuclein and is the focus of the worldwide collaboration with Roche

- Part 1 of the Phase 2 PASADENA study in patients with early Parkinson's disease (N=316) being conducted by Roche is complete. Based on ongoing evaluation of Part 1 PASADENA study data, including potential discussions with health authorities, a further update on prasinezumab is expected later this year.
- The 52-week blinded extension of the study (Part 2 of the Phase 2 PASADENA Study) is ongoing. Due to the COVID-19 pandemic, patients have missed assessments in Part 2 of the study. The full extent of the COVID-19 disruption to Part 2 is not yet known.

**PRX004**, a potential treatment for ATTR amyloidosis, is a monoclonal antibody designed to deplete the pathogenic, non-native forms of the TTR protein

- The Phase 1 study of PRX004 is fully enrolled and as of early March patients in all 6 cohorts had received the three infusions and assessments that comprise the dose-escalation portion of the study. Interim data from cohorts 1 through 5 was reported in December.
- At the conclusion of the dose-escalation portion of the study, patients meeting eligibility requirements were provided the option to enroll in the long-term-extension (LTE) portion of the study, which allows for up to 15 additional infusions per patient and is designed to further assess safety, tolerability, pharmacokinetics and pharmacodynamics of PRX004. The LTE also includes certain clinical outcome measures for patients in cohorts 4 through 6 at the month 10 assessment (prior to infusion) and at the end of study (month 19 assessment). As of early April, patients in cohorts 1 through 5 in the LTE had completed at least their month 12 assessment and one patient in cohort 6 had completed their month 10 assessment.
- Because of the disruptions caused by the COVID-19 pandemic, some patients have had to discontinue from the study and most patients in the LTE portion of the study have missed at least one infusion and/or assessment. . The Company continues to monitor the impact that COVID-19 will have on the LTE portion of the study based on the fluid circumstances at each of the sites in the United States and Europe. If the COVID-19 pandemic results in missed visits over a prolonged period, it is possible that more patients may not be able to complete the LTE portion of the study.
- The Company believes the study has advanced sufficiently to determine next steps for the program and has begun further clinical development planning activities. The Company currently expects additional data from the dose-escalation and LTE portions of the study, as well as an update on next steps for clinical development, to be reported later this year. This timing, however, is dependent on any additional impacts of COVID-19.

**Discovery and Preclinical Development**: Prothena is advancing an early-stage pipeline of programs for a number of potential neurological indications

- The Company continues to expect to advance IND-enabling activities in 2020 for our preclinical tau program, part of a global neuroscience collaboration with Bristol-Myers Squibb
- The Company continues to expect to initiate IND-enabling activities in 2020 for our preclinical Aβ program

**First Quarter 2020 Financial Results and Updated 2020 Financial Guidance**

For the first quarter of 2020, Prothena reported a net loss of $23.6 million, as compared to a net loss of $20.9 million for the first quarter of 2019, which included a restructuring credit of $0.1 million in the first quarter of 2019 resulting from an adjustment in previously recorded employee termination benefits associated with the discontinuation of the

NEOD001 program. Net loss per share for the first quarter of 2020 was $0.59, as compared to a net loss per share of $0.52 for the first quarter of 2019.

Prothena reported total revenue, all from its collaboration with Roche, of $0.1 million for the first quarter of 2020, as compared to total revenue of $0.2 million for the first quarter of 2019.

Research and development (R&D) expenses totaled $15.2 million for the first quarter of 2020, as compared to $13.3 million for the first quarter of 2019. The increase in R&D expense for the first quarter of 2020 compared to the same period in the prior year was primarily due to higher collaboration expense with Roche, higher manufacturing costs (primarily related to the tau and Aβ programs) and higher clinical trial costs (primarily associated with the PRX004 program). R&D expenses included non-cash share-based compensation expense of $2.0 million for the first quarter of 2020, as compared to $2.1 million for the first quarter of 2019.

General and administrative (G&A) expenses totaled $9.7 million for the first quarter of 2020, as compared to $9.9 million for first quarter of 2019. G&A expenses for the first quarter of 2020 decreased compared to the same period in the prior year primarily related to lower personnel costs (including share-based compensation expense), and lower legal and accounting fees, which was offset in part by higher costs for our director and officer insurance premiums. G&A expenses included non-cash share-based compensation expense of $3.5 million for the first quarter of 2020, as compared to $4.1 million for the first quarter of 2019.

Total non-cash share-based compensation expense was $5.5 million for the first quarter of 2020, as compared to $6.2 million for the first quarter of 2019.

As of March 31, 2020, Prothena had $355.4 million in cash, cash equivalents and restricted cash and no debt.

As of May 1, 2020, Prothena had approximately 39.9 million ordinary shares outstanding.

The Company is updating its projected full year 2020 net cash burn from operating and investing activities, and expects it to be $75 to $85 million (versus prior guidance of $60 to $76 million), and expects to end the year with approximately $299 million (midpoint) in cash, cash equivalents and restricted cash (cash position), representing a decrease of $11 million from prior guidance of $310 million (midpoint). This decrease in cash position is primarily driven by an increase in expenses related to further clinical development, planning activities and ongoing evaluation of data from the Phase 2 PASADENA study of prasinezumab, and is based on Prothena's 30% portion of the U.S. co-development expenses. The updated estimated full year 2020 net cash burn from operating and investing activities is primarily driven by an updated estimated net loss of $101 to $118 million (versus prior guidance of $84 to $106 million), which includes an estimated $23 million of non-cash share-based compensation expense.

**About Prothena**

Prothena Corporation plc is a clinical-stage neuroscience company with expertise in protein misfolding, focused on the discovery and development of novel therapies with the potential to fundamentally change the course of devastating diseases. Fueled by its deep scientific expertise built over decades of research, Prothena is advancing a pipeline of therapeutic candidates for a number of indications and novel targets for which its ability to integrate scientific insights around neurological dysfunction and the biology of misfolded proteins can be leveraged. Prothena's partnered programs include prasinezumab (PRX002/RG7935), in collaboration with Roche for the potential treatment of Parkinson's disease and other related synucleinopathies, and programs that target tau, TDP-43 and an undisclosed target in collaboration with Bristol-Myers Squibb for the potential treatment of Alzheimer's disease, amyotrophic lateral sclerosis (ALS), frontotemporal dementia (FTD) or other neurodegenerative diseases. Prothena's proprietary programs include PRX004 for the potential treatment of ATTR amyloidosis, and programs that target Aβ (Amyloid beta) for the potential treatment of Alzheimer's disease. For more information, please visit the Company's website at www.prothena.com and follow the Company on Twitter @ProthenaCorp.

**Forward-looking Statements**

*This press release contains forward-looking statements. These statements relate to, among other things, the sufficiency of our cash position to fund advancement of a broad pipeline; the treatment potential and proposed mechanisms of action of prasinezumab and PRX004; plans for the ongoing Phase 2 clinical study of prasinezumab and the ongoing Phase 1 clinical study of PRX004; the expected timing of reporting data from the Phase 1 clinical study of PRX004 and from the Phase 2 clinical study of prasinezumab; the continued advancement of our discovery and preclinical pipeline; the timing of IND-enabling activities from our tau and* Aβ *programs; our anticipated net cash burn from operating and investing activities for 2020 and expected cash balance at the end of 2020; and our estimated net loss and non-cash share-based compensation expense for 2020. 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 effects on our business of the worldwide COVID-19 pandemic and the risks, uncertainties and other factors described in the "Risk Factors" sections of our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 3, 2020, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission.. 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.*

**PROTHENA CORPORATION PLC**
**CONSOLIDATED STATEMENTS OF OPERATIONS**
**(unaudited - amounts in thousands except per share data)**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| Collaboration revenue | $ 141 | $ 186 |
| Total revenue | 141 | 186 |
| Operating expenses: | | |
| Research and development | 15,248 | 13,296 |
| General and administrative | 9,741 | 9,905 |
| Restructuring credits | — | (61) |
| Total operating expenses | 24,989 | 23,140 |
| Loss from operations | (24,848) | (22,954) |
| Other income, net | 1,113 | 2,287 |
| Loss before income taxes | (23,735) | (20,667) |
| Provision for (benefit from) income taxes | (166) | 198 |
| Net loss | $ (23,569) | $ (20,865) |
| Basic and diluted net loss per share | $ (0.59) | $ (0.52) |
| Shares used to compute basic and diluted net loss per share | 39,909 | 39,864 |

**PROTHENA CORPORATION PLC**
**CONSOLIDATED BALANCE SHEETS**
**(unaudited - amounts in thousands)**

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| **Assets** | | |
| Cash and cash equivalents | $ 352,685 | $ 375,723 |
| Accounts receivable | 174 | 68 |
| Prepaid expenses and other current assets | 6,832 | 2,584 |
| Total current assets | 359,691 | 378,375 |
| Property and equipment, net | 3,531 | 3,874 |
| Operating lease right-of-use assets | 21,929 | 23,274 |
| Restricted cash, non-current | 2,704 | 2,704 |
| Other non-current assets | 11,566 | 11,041 |
| Total non-current assets | 39,730 | 40,893 |
| Total assets | $ 399,421 | $ 419,268 |
| **Liabilities and Shareholders' Equity** | | |
| Accrued research and development | $ 5,223 | $ 5,826 |
| Lease liability, current | 5,202 | 5,101 |
| Other current liabilities | 6,661 | 6,787 |
| Total current liabilities | 17,086 | 17,714 |
| Deferred revenue | 110,242 | 110,242 |
| Lease liability, non-current | 16,501 | 17,838 |
| Other non-current liabilities | 553 | 553 |
| Total non-current liabilities | 127,296 | 128,633 |
| Total liabilities | 144,382 | 146,347 |
| Total shareholders' equity | 255,039 | 272,921 |
| Total liabilities and shareholders' equity | $ 399,421 | $ 419,268 |

## Media and Investor Contact:

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