

**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): August 6, 2020

PROTHENA CORPORATION PUBLIC LIMITED COMPANY
(Exact name of registrant as specified in its charter)

Ireland
(State or Other Jurisdiction
of Incorporation)

001-35676
(Commission
File Number)

98-111119
(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

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

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))

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

<u>Title of Each Class</u>	<u>Trading Symbol</u>	<u>Name of Each Exchange on Which Registered</u>
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

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 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 August 6, 2020, Prothena Corporation plc issued a press release announcing its financial results for the second quarter ended June 30, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated August 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: August 6, 2020

PROTHENA CORPORATION PLC

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



Prothena Reports Second Quarter 2020 Financial Results and Provides R&D Update

- **Net cash used in operating and investing activities was \$18.7 million in the second quarter and \$41.9 million for the first six months of 2020; quarter-end cash and restricted cash position of \$336.6 million provides funding to advance a broad pipeline**

DUBLIN, Ireland, August 6, 2020-- Prothena Corporation plc (NASDAQ:PRTA), a clinical-stage company with expertise in protein dysregulation and a diverse pipeline of investigational therapeutics for neurodegenerative and rare peripheral amyloid diseases, today reported financial results for the second quarter and first six months of 2020. In addition, the Company provided an update on its R&D programs.

“We continue to expect multiple clinical data read-outs later this year across our pipeline,” said Gene Kinney, Ph.D., President and Chief Executive Officer of Prothena. “New data from Part 1 of the Phase 2 prasinezumab study (PASADENA) in Parkinson’s disease, being conducted by Roche will be presented in an oral presentation next month at the Movement Disorders Society congress, and additional data from our Phase 1 study of PRX004 in ATTR amyloidosis are expected in the fourth quarter. In addition, we are making excellent progress on our early-stage pipeline targeting a range of neurological indications and look forward to sharing preclinical data from programs in our Alzheimer’s disease portfolio later this year.”

Second Quarter 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. Results from Part 1 of the study have been selected as an oral Top Abstract presentation at the upcoming virtual International Congress of Parkinson's Disease and Movement Disorders Society (MDS) on September 14, 2020.
- The 52-week blinded extension of the study (Part 2 of the Phase 2 PASADENA Study) is ongoing. COVID-19 has caused some participants to miss assessments in Part 2 of the study. Mitigation efforts have been put in place to ensure patient safety, and the situation is improving in most geographies. Roche continues to monitor the situation carefully to minimize patient risk and the impact on the study.

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

- Since interim data from cohorts 1 through 5 were reported in December, patients in all 6 cohorts of the Phase 1 study of PRX004 have received the three infusions and assessments that comprised the dose-escalation portion of the study.
- The long-term extension (LTE) portion of the study, which allowed for up to 15 additional infusions, experienced disruptions due to the COVID-19 pandemic. However, 6 patients in cohorts 4 and 5, and 1 patient in cohort 6 completed one post-baseline neuropathy assessment following 9 months of PRX004 administration.

- The Company expects to report new data in the fourth quarter of this year from the dose-escalation and available LTE portion of the study. This timing, however, is dependent on ongoing COVID-19 restrictions at clinical study sites that can impact data collection and analyses.
- The Company continues to believe that the study has advanced sufficiently to determine next steps for the program, and has begun further clinical development planning activities, expecting to disclose next steps in the fourth quarter of this year.

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 A β program.

Upcoming Investor Conference

Members of the senior management team will present and participate in investor meetings at the following upcoming investor conferences:

- BTIG Virtual Biotechnology Conference 2020 on August 11, 2020 at 1:00PM Eastern Time

A live webcast of the presentations can be accessed through the Investors section of the Company's website at www.prothena.com. Following the live presentations, a replay of the webcast will be available on the Company's website for at least 90 days following the presentation date.

Second Quarter and First Six Months of 2020 Financial Results

For the second quarter and first six months of 2020, Prothena reported a net loss of \$26.3 million and \$49.9 million, respectively, as compared to a net loss of \$15.8 million and \$36.7 million for the second quarter and first six months of 2019, respectively. The second quarter and first six months of 2019 included a restructuring credit of nil and \$0.1 million, respectively, which resulted from an adjustment in previously recorded employee termination benefits associated with the discontinuation of the NEOD001 program. Net loss per share for the second quarter and first six months of 2020 was \$0.66 and \$1.25, respectively, as compared to a net loss per share of \$0.40 and \$0.92 for the second quarter and first six months 2019, respectively.

Prothena reported total revenue, primarily from its collaboration with Roche, of \$0.2 million and \$0.3 million for the second quarter and first six months of 2020, respectively as compared to total revenue of \$0.2 million and \$0.4 million for the second quarter and first six months of 2019, respectively.

Research and development (R&D) expenses totaled \$17.3 million and \$32.5 million for the second quarter and first six months of 2020, respectively, as compared to \$9.6 million and \$22.9 million for the second quarter and first six months of 2019, respectively. The increase in R&D expense for the second quarter and first six months of 2020 compared to the same periods in the prior year was primarily due to higher collaboration expense with Roche related to the prasinezumab program and higher manufacturing costs (primarily related to the tau, A β and PRX004 programs). R&D expenses included non-cash share-based compensation expense of \$2.1 million and \$4.1 million for the second quarter and first six months of 2020, respectively, as compared to \$2.1 million and \$4.2 million for the second quarter and first six months of 2019, respectively.

General and administrative (G&A) expenses totaled \$9.7 million and \$19.4 million for the second quarter and first six months of 2020, respectively, as compared to \$9.1 million and \$19.0 million for the second quarter and first six months of 2019, respectively. The increase in G&A expenses for the second quarter and first six months of 2020 compared to the same periods in the prior year primarily related to higher costs for our director and officer

insurance premiums and higher legal and accounting fees offset in part by lower personnel costs (including share-based compensation expense). G&A expenses included non-cash share-based compensation expense of \$3.6 million and \$7.1 million for the second quarter and first six months of 2020, respectively, as compared to \$4.2 million and \$8.3 million for the second quarter and first six months of 2019, respectively.

Total non-cash share-based compensation expense was \$5.7 million and \$11.2 million for the second quarter and first six months of 2020, respectively, as compared to \$6.3 million and \$12.5 million for the second quarter and first six months of 2019, respectively.

As of June 30, 2020, Prothena had \$336.6 million in cash, cash equivalents and restricted cash and no debt.

As of July 31, 2020, Prothena had approximately 39.9 million ordinary shares outstanding.

The Company continues to expect its full year 2020 net cash burn from operating and investing activities to be \$75-\$85 million, and expects to end the year with approximately \$299 million in cash, cash equivalents and restricted cash (midpoint). The estimated full year 2020 net cash burn from operating and investing activities is primarily driven by estimated net loss of \$101-\$118 million, which includes an estimated \$23 million of non-cash share-based compensation expense.

Inducement Grant Under NASDAQ Listing Rule 5635(C)(4)

In connection with hiring an employee, the compensation committee of the Company's board of directors granted the individual hired by the Company an option to purchase 60,000 ordinary shares of the Company. The stock option has an exercise price per share equal to \$12.76, which was the closing trading price on August 3, 2020, the date of the grant. The inducement award will vest over four years, with 25% of the underlying shares vesting on the one-year anniversary of the date of grant and 1/48th of the underlying shares vesting monthly thereafter over 36 months. The stock option was granted pursuant to the Company's 2020 Employment Inducement Incentive Plan, which was approved by the Company's board of directors under Rule 5635(c)(4) of The Nasdaq Global Market for equity grants to induce new employees to enter into employment with the Company.

About Prothena

Prothena Corporation plc is a clinical-stage company with expertise in protein dysregulation and a diverse pipeline of novel investigational therapeutics with the potential to change the course of devastating neurodegenerative and rare peripheral amyloid 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 A β (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 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; plans for future clinical studies of prasinezumab and PRX004; the continued advancement of our discovery and preclinical pipeline; the timing of IND-enabling activities from our tau and A β 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 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Collaboration revenue	\$ 145	\$ 167	\$ 286	\$ 353
License revenue	50	—	50	—
Total revenue	195	167	336	353
Operating expenses:				
Research and development	17,271	9,583	32,519	22,879
General and administrative	9,656	9,081	19,397	18,986
Restructuring credits	—	—	—	(61)
Total operating expenses	26,927	18,664	51,916	41,804
Loss from operations	(26,732)	(18,497)	(51,580)	(41,451)
Other income, net	195	2,531	1,308	4,818
Loss before income taxes	(26,537)	(15,966)	(50,272)	(36,633)
Provision for (benefit from) income taxes	(255)	(156)	(421)	42
Net loss	\$ (26,282)	\$ (15,810)	\$ (49,851)	\$ (36,675)
Basic and diluted net loss per share	\$ (0.66)	\$ (0.40)	\$ (1.25)	\$ (0.92)
Shares used to compute basic and diluted net loss per share	39,911	39,872	39,910	39,868

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

	June 30, 2020	December 31, 2019
Assets		
Cash and cash equivalents	\$ 333,942	\$ 375,723
Accounts receivable	56	68
Prepaid expenses and other current assets	7,125	2,584
Total current assets	341,123	378,375
Property and equipment, net	3,215	3,874
Operating lease right-of-use assets	20,570	23,274
Restricted cash, non-current	2,704	2,704
Other non-current assets	11,321	11,041
Total non-current assets	37,810	40,893
Total assets	\$ 378,933	\$ 419,268
Liabilities and Shareholders' Equity		
Accrued research and development	\$ 6,152	\$ 5,826
Lease liability, current	5,304	5,101
Other current liabilities	7,088	6,787
Total current liabilities	18,544	17,714
Deferred revenue	110,242	110,242
Lease liability, non-current	15,150	17,838
Other non-current liabilities	553	553
Total non-current liabilities	125,945	128,633
Total liabilities	144,489	146,347
Total shareholders' equity	234,444	272,921
Total liabilities and shareholders' equity	\$ 378,933	\$ 419,268

Media and Investor Contact:

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