

**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, 2019

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)

98-1111119
(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, 2019, Prothena Corporation plc issued a press release announcing its financial results for the second quarter ended June 30, 2019. 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, 2019

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, 2019

PROTHENA CORPORATION PLC

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



Prothena Reports Second Quarter 2019 Financial Results and Provides R&D Update

- **Net cash used in operating and investing activities was \$12.2 million in the second quarter and \$29.7 million for the first six months of 2019; quarter-end cash and restricted cash position of \$402.2 million provides funding to advance neuroscience pipeline**
- **Appointed Paula K. Cobb to Prothena's Board of Directors and Michael J. Malecek as Prothena's Chief Legal Officer and Company Secretary**

DUBLIN, Ireland, August 6, 2019 -- Prothena Corporation plc (NASDAQ:PRTA), a clinical-stage neuroscience company, today reported financial results for the second quarter and first six months of 2019. In addition, the Company provided an update on its R&D programs.

"We remain on track to report interim clinical data from the Phase 1 study of PRX004 for ATTR amyloidosis in the fourth quarter of this year, and results from Part 1 of the PASADENA Phase 2 study of prasinezumab for Parkinson's disease are expected in 2020," said Gene Kinney, Ph.D., President and Chief Executive Officer of Prothena. "Recently, we welcomed Paula Cobb to our Board of Directors and Mike Malecek as our Chief Legal Officer and Company Secretary. We look forward to their expertise contributing to our progress as we advance our pipeline of therapeutic candidates for devastating neurological diseases."

Mr. Malecek's appointment was made in conjunction with the retirement of Arthur W. ("Bill") Homan that was announced in 2018. "Since joining Prothena in 2014, Bill provided expert leadership across several business domains, and on behalf of the entire Prothena team and Board we are thankful for his significant contributions and wish him and his family all the best in his retirement," continued Dr. Kinney.

"I am excited to join Prothena and have this uniquely rewarding opportunity to contribute as part of a team dedicated to advancing novel therapies for patients with neurological diseases," commented Mike Malecek, Chief Legal Officer and Company Secretary of Prothena.

Second Quarter 2019 and Recent Developments

- Appointed Paula K. Cobb to Prothena's Board of Directors. Ms. Cobb is the Chief Operating Officer of Decibel Therapeutics, Inc., and has extensive global development, business strategy and commercial experience. Prior to joining Decibel in 2016, Ms. Cobb worked in a variety of global leadership roles at Biogen, including as Senior Vice President of the rare disease group, where she was responsible for the company's marketed hemophilia assets and Phase 3 programs in spinal muscular atrophy and neuropathic pain. She served on the board of directors of Nightstar Therapeutics plc, a clinical-stage gene therapy company, until its acquisition by Biogen.
 - Appointed Michael J. Malecek as Chief Legal Officer and Company Secretary. Prior to joining Prothena, Mr. Malecek was Vice President and Deputy General Counsel of Intellectual Property & Litigation at Snowflake Computing. Previously, he was a Partner at the law firms of Arnold & Porter Kaye Scholer, Kaye Scholer and Dewey & LeBoeuf. In these positions he served as Managing Partner of the Silicon Valley offices and represented a range of life science companies, including Affymetrix and Complete Genomics, on intellectual
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property, compliance and securities law matters. Mr. Malecek's experience in the life science industry also includes six years as Vice President and Chief Advocacy Counsel at Affymetrix.

Upcoming Research and Development Milestones

Prothena is advancing a neuroscience pipeline of therapeutic candidates for a number of indications.

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

- The Phase 2 PASADENA study in patients with early Parkinson's disease was fully enrolled in December 2018 (N=316) and is being conducted by Roche. Data from Part 1 of the PASADENA study are expected to be announced in 2020

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

- The Phase 1 study of PRX004 continues to enroll patients with hATTR amyloidosis, and preliminary data from the first four of six dose level cohorts (0.1 mg/kg, 0.3 mg/kg, 1.0 mg/kg, 3.0 mg/kg, 10.0 mg/kg and 30.0 mg/kg), including safety, tolerability and pharmacodynamics, as measured by Prothena's proprietary misTTR assay, are expected to be announced in the fourth quarter of 2019

Tau is a protein implicated in diseases including Alzheimer's disease (AD), progressive supranuclear palsy (PSP), frontotemporal dementia (FTD) and chronic traumatic encephalopathy (CTE). Prothena's internally discovered tau antibody targets a novel epitope on the protein.

- The preclinical tau program, part of a worldwide collaboration with Celgene, initiated cell line development of a lead candidate in the second quarter of this year

Second Quarter and First Six Months of 2019 Financial Results

For the second quarter and first six months of 2019, Prothena reported a net loss of \$15.8 million and \$36.7 million, respectively, as compared to a net loss of \$59.9 million and \$108.6 million for the second quarter and first six months of 2018, which included restructuring charges of \$20.9 million associated with the discontinuation of the NEOD001 program. Net loss per share for the second quarter and first six months of 2019 was \$0.40 and \$0.92, respectively, as compared to a net loss per share of \$1.50 and \$2.77 for the second quarter and first six months of 2018, respectively.

Prothena reported total revenue, all from its collaboration with Roche, of \$0.2 million and \$0.4 million for the second quarter and first six months of 2019, respectively, as compared to total revenue of \$0.3 million and \$0.5 million for the second quarter and first six months of 2018, respectively.

Research and development (R&D) expenses totaled \$9.6 million and \$22.9 million for the second quarter and first six months of 2019, respectively, as compared to \$31.5 million and \$66.2 million for the second quarter and first six months of 2018, respectively. The decrease in R&D expenses for the second quarter and the first six months compared to the same periods in the prior year was primarily due to lower clinical trial costs and to a lesser extent lower product manufacturing expenses, lower personnel costs and lower consulting costs. R&D expenses included non-cash share-based compensation expense of \$2.1 million and \$4.2 million for the second quarter and first six months of 2019, respectively, as compared to \$2.6 million and \$4.8 million for the second quarter and first six months of 2018, respectively.

General and administrative (G&A) expenses totaled \$9.1 million and \$19.0 million for the second quarter and first six months of 2019, respectively, as compared to \$11.0 million and \$25.2 million for second quarter and first six months of 2018, respectively. The decrease in G&A expenses for the second quarter and the first six months compared to the same periods in the prior year was primarily due to lower personnel costs, sublease rental income and lower legal expenses. G&A expenses included non-cash share-based compensation expense of \$4.2 million and \$8.3 million for

the second quarter and first six months of 2019, respectively, as compared to \$3.8 million and \$8.4 million for the second quarter and first six months of 2018, respectively.

Total non-cash share-based compensation expense was \$6.3 million and \$12.5 million for the second quarter and first six months of 2019 respectively, as compared to \$8.8 million and \$15.7 million for the second quarter and first six months of 2018, respectively, which included \$2.5 million of non-cash share-based compensation expense included in the restructuring costs.

As of June 30, 2019, Prothena had \$402.2 million in cash, cash equivalents and restricted cash and no debt.

As of July 19, 2019, Prothena had approximately 39.9 million ordinary shares outstanding.

The Company continues to expect its full year 2019 net cash burn from operating and investing activities to be \$57-65 million, and to end the year with approximately \$371 million in cash, cash equivalents and restricted cash (midpoint). The estimated full year 2019 cash burn from operating and investing activities is primarily driven by an estimated net loss of \$83-94 million, which includes an estimated \$24 million of non-cash share-based compensation expense.

About Prothena

Prothena Corporation plc is a clinical-stage neuroscience company focused on the discovery and development of novel therapies with the potential to fundamentally change the course of devastating neurological disorders. Fueled by its deep scientific understanding built over decades of neuroscience research, Prothena is advancing a pipeline of therapeutic candidates for a number of indications and novel targets including Parkinson's disease and other related synucleinopathies (prasinezumab - PRX002/RG7935, in collaboration with Roche) and ATTR amyloidosis (PRX004), as well as tau and TDP-43 (both programs in collaboration with Celgene) for which its scientific understanding of disease pathology can be leveraged. For more information, please visit the Company's website at www.prothena.com and follow us on Twitter @ProthenaCorp.

Forward-looking Statements

This press release contains forward-looking statements. These statements relate to, among other things: the sufficiency of our funding to advance our neuroscience pipeline; our expected timing of reporting interim data from the Phase 1 study of PRX004 and the expected scope of that data; our expected timing of reporting data from the Phase 2 PASADENA study of prasinezumab; the design of prasinezumab and its potential as a treatment for Parkinson's disease; the design of PRX004 and its potential as a treatment for ATTR amyloidosis; our goal of advancing a neuroscience pipeline of therapeutic candidates for a number of indications; our expected net cash burn from operating and investing activities in 2019 and cash balance at the end of 2019; and our estimated net loss and non-cash share-based compensation expense for 2019. 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 our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) March 15, 2019 and our 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.

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,	
	2019	2018	2019	2018
Collaboration revenue	\$ 167	\$ 279	\$ 353	\$ 506
Total revenue	167	279	353	506
Operating expenses:				
Research and development	9,583	31,452	22,879	66,158
General and administrative	9,081	10,992	18,986	25,221
Restructuring charges (credits)	—	20,904	(61)	20,904
Total operating expenses	18,664	63,348	41,804	112,283
Loss from operations	(18,497)	(63,069)	(41,451)	(111,777)
Other income, net	2,531	1,241	4,818	1,169
Loss before income taxes	(15,966)	(61,828)	(36,633)	(110,608)
Provision for (benefit from) income taxes	(156)	(1,946)	42	(1,983)
Net loss	\$ (15,810)	\$ (59,882)	\$ (36,675)	\$ (108,625)
Basic and diluted net loss per share	\$ (0.40)	\$ (1.50)	\$ (0.92)	\$ (2.77)
Shares used to compute basic and diluted net loss per share	39,872	39,824	39,868	39,257

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

	June 30,	December 31,
	2019	2018
Assets		
Cash and cash equivalents	\$ 398,144	\$ 427,659
Restricted cash, current	1,352	—
Prepaid expenses and other current assets	19,212	3,731
Total current assets	418,708	431,390
Property and equipment, net	4,318	52,835
Operating lease right-of-use assets	25,927	—
Restricted cash, non-current	2,704	4,056
Other non-current assets	10,415	10,515
Total non-current assets	43,364	67,406
Total assets	<u>\$ 462,072</u>	<u>\$ 498,796</u>
Liabilities and Shareholders' Equity		
Accrued research and development	\$ 2,260	\$ 5,370
Restructuring liability	—	461
Lease liability, current	4,904	—
Other current liabilities	20,852	9,095
Total current liabilities	28,016	14,926
Deferred revenue	110,242	110,242
Lease liability, non-current	20,454	—
Other non-current liabilities	553	50,630
Total non-current liabilities	131,249	160,872
Total liabilities	159,265	175,798
Total shareholders' equity	302,807	322,998
Total liabilities and shareholders' equity	<u>\$ 462,072</u>	<u>\$ 498,796</u>

Media and Investor Contact:

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