

**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): May 7, 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))

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.

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

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 7, 2019, Prothena Corporation plc issued a press release announcing its financial results for the first quarter ended March 31, 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 May 7, 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: May 7, 2019

PROTHENA CORPORATION PLC

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



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

- **Net cash used in operating and investing activities was \$17.6 million in the first quarter; quarter-end cash and restricted cash position of \$414.2 million provides funding to advance neuroscience pipeline**
- **Initiated cell line development of a lead candidate for preclinical tau program**

DUBLIN, Ireland, May 7, 2019 -- Prothena Corporation plc (NASDAQ:PRTA), a clinical-stage neuroscience company, today reported financial results for the first quarter of 2019. In addition, the Company provided an update on its R&D programs and 2019 financial guidance.

“We continue to advance our neuroscience pipeline of investigational therapies, and are progressing several programs towards key milestones,” said Gene Kinney, Ph.D., President and Chief Executive Officer of Prothena. “We have initiated cell line development of a lead candidate for our tau program under our collaboration with Celgene. Enrollment in our Phase 1 study of PRX004 in ATTR amyloidosis is progressing and we now anticipate that the fourth quarter update on this program will include data from cohorts 1 through 4. Data from Part 1 of the Phase 2 PASADENA study of prasinezumab in Parkinson’s disease, which is being run by Roche, are expected in 2020. We also recently reported results from the Phase 3 VITAL study of NEOD001 in AL amyloidosis and are exploring business development opportunities that could result in further clinical investigation of NEOD001.”

First Quarter 2019 and Recent Development

NEOD001 (birtamimab) is an investigational humanized immunoglobulin G1 designed to directly neutralize soluble toxic aggregates and promote clearance of amyloid via phagocytosis to remove organ-deposited amyloid thought to cause organ dysfunction in patients with AL amyloidosis.

- [Reported results](#) from the Phase 3 VITAL Amyloidosis Study of NEOD001 (birtamimab) in newly diagnosed, treatment naïve patients with AL amyloidosis and cardiac dysfunction (N=260), which was discontinued in 2018. The final hazard ratio (HR) for the composite primary endpoint (time to all-cause mortality or time to cardiac hospitalization more than 90 days after first infusion of study drug) of 0.835 (95% CI: 0.5799, 1.2011; p=0.330) was consistent with the futility analysis reported in April 2018. Post hoc analyses of all-cause mortality revealed a potential survival benefit favoring NEOD001 in the category of patients at highest risk for early mortality (Mayo Stage IV, n=77) with a HR of 0.544 (95% CI: 0.2738, 1.0826; p=0.0787). This potential survival benefit was more pronounced in Mayo Stage IV patients during the initial 12 months of treatment, with a HR of 0.498 (95% CI: 0.2404, 1.0304; p=0.0556).

Upcoming Research and Development Milestones

Prothena is advancing a pipeline of therapeutic candidates for a number of indications and novel targets.

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 (N=316) is being conducted by Roche and data from Part 1 of this study are expected in 2020

PRX004, a potential treatment for ATTR amyloidosis, is a monoclonal antibody designed to target and clear the pathogenic, misfolded 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 (0.1mg/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, are expected 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

First Quarter 2019 Financial Results and Updated 2019 Guidance

Prothena reported a net loss of \$20.9 million for the first quarter of 2019, as compared to a net loss of \$48.7 million for the first quarter of 2018. Net loss per share for the first quarter of 2019 was \$0.52, as compared to a net loss per share of \$1.26 for the first quarter of 2018.

Prothena reported total revenue from its collaboration with Roche of \$0.2 million for the first quarter of 2019 as compared to total revenue of \$0.2 million for the first quarter of 2018.

Research and development (R&D) expenses totaled \$13.3 million for the first of 2019, as compared to \$34.7 million for the first quarter 2018. The decrease in R&D expenses compared to the first quarter of 2018 was primarily due to lower clinical trial costs, lower consulting and personnel costs and lower product manufacturing expenses. R&D expenses included non-cash share-based compensation expense of \$2.1 million for the first quarter 2019 as compared to \$2.3 million for the first quarter of 2018.

General and administrative (G&A) expenses totaled \$9.9 million for the first quarter of 2019, as compared to \$14.2 million for the first quarter of 2018. The decrease in G&A expenses compared to the first quarter of 2018 was primarily due to lower personnel costs and consulting expenses. G&A expenses included non-cash share-based compensation expense of \$4.1 million for the first quarter of 2019, as compared to \$4.6 million for the first quarter of 2018.

Total non-cash share-based compensation expense was \$6.2 million for the first quarter of 2019, as compared to \$6.9 million for the first quarter 2018.

As of March 31, 2019, Prothena had \$414.2 million in cash, cash equivalents and restricted cash and no debt.

As of April 30, 2019, Prothena had approximately 39.9 million ordinary shares outstanding.

The Company is updating its full year 2019 net cash burn from operating and investing activities, and expects it to be \$57-65 million, representing a decrease of approximately \$7 million, and expects to end the year with approximately \$371 million in cash, cash equivalents and restricted cash (midpoint). The Company had planned on initiating cell line development of a lead candidate for an Amyloid beta discovery program this year but will not be making additional investments in this program at this time based on the recent discontinuation of Biogen's aducanumab program. The updated estimated full year 2019 cash burn from operating and investing activities is primarily driven by an updated estimated net loss of \$83-94 million, which includes an estimated \$24 million of non-cash shared-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 progressive, life-threatening diseases. 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) and ATTR amyloidosis (PRX004), as well as tau and TDP-43 where 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; the progress of our neuroscience pipeline of investigational therapies towards key milestones; our expected timing of reporting data from the Phase 2 PASADENA study of prasinezumab; our expected timing of reporting data from the Phase 1 study of PRX004 and the expected scope of that data; our exploration of business development opportunities that could result in further clinical investigation of NEOD001; the design and proposed mechanisms of action of NEOD001 and its potential as a treatment for AL amyloidosis; the results of post hoc analyses that reveal a potential survival benefit favoring NEOD001; 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 research pipeline of novel targets for a number of potential 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 March 31,	
	2019	2018
Collaboration revenue	\$ 186	\$ 227
Total revenue	186	227
Operating expenses:		
Research and development	13,296	34,706
General and administrative	9,905	14,229
Restructuring charges (credits)	(61)	—
Total operating expenses	23,140	48,935
Loss from operations	(22,954)	(48,708)
Other income (expense), net	2,287	(72)
Loss before income taxes	(20,667)	(48,780)
Provision for (benefit from) income taxes	198	(37)
Net loss	\$ (20,865)	\$ (48,743)
Basic and diluted net loss per share	\$ (0.52)	\$ (1.26)
Shares used to compute basic and diluted net loss per share	39,864	38,684

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

	March 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	\$ 410,106	\$ 427,659
Restricted cash, current	1,352	—
Prepaid expenses and other current assets	3,735	3,731
Total current assets	415,193	431,390
Property and equipment, net	4,632	52,835
Operating lease right-of-use assets	27,234	—
Restricted cash, non-current	2,704	4,056
Other assets	9,771	10,515
Total non-current assets	44,341	67,406
Total assets	\$ 459,534	\$ 498,796
Liabilities and Shareholders' Equity		
Accrued research and development	\$ 4,738	\$ 5,370
Restructuring liability	—	461
Operating lease liability, current	4,810	—
Other current liabilities	5,358	9,095
Total current liabilities	14,906	14,926
Deferred revenue	110,242	110,242
Operating lease liability, non-current	21,703	—
Other non-current liabilities	553	50,630
Total non-current liabilities	132,498	160,872
Total liabilities	147,404	175,798
Total shareholders' equity	312,130	322,998
Total liabilities and shareholders' equity	\$ 459,534	\$ 498,796

Media and Investor Contact:

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