

PROTHENA CORP PLC

FORM 8-K (Current report filing)

Filed 05/08/18 for the Period Ending 05/08/18

Telephone	011-353-1-236-2500
CIK	0001559053
Symbol	PRTA
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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 8, 2018

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.)

**Adelphi Plaza
Upper George's Street
Dún Laoghaire
Co. Dublin, A96 T927, 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.

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 8, 2018 , Prothena Corporation plc issued a press release announcing its financial results for the first quarter ended March 31, 2018 . 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 8, 2018.

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 8, 2018

PROTHENA CORPORATION PLC

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



Prothena Reports First Quarter 2018 Financial Results and Provides R&D Update

- **Net cash used in operating and investing activities was \$31.8 million in the first quarter; quarter-end cash and restricted cash position of \$433.1 million supports advancement through key milestones of R&D pipeline**
- **Entered into global neuroscience research & development collaboration with Celgene to advance novel therapies for patients with neurodegenerative diseases**
- **Initiated a first-in-human study of PRX004 in patients with ATTR amyloidosis**

DUBLIN, Ireland - May 8, 2018 - Prothena Corporation plc (NASDAQ:PRTA), a clinical-stage biotechnology company focused on the discovery and development of novel therapies in the neuroscience and orphan categories, today reported financial results for the first quarter of 2018. In addition, the Company provided an update on its R&D programs.

“We are moving several programs in our clinical and discovery pipeline forward and have recently initiated a Phase 1 study of PRX004 in patients with ATTR amyloidosis,” said Gene Kinney, PhD, President and Chief Executive Officer of Prothena. “Through our recently announced neuroscience R&D collaboration with Celgene, we are advancing three discovery programs that target a broad range of neurodegenerative diseases. While we recently discontinued development of NEOD001, we remain focused on pursuing new and better treatment options for patients through a scientifically rigorous approach in our research and development efforts.”

First Quarter 2018 and Recent Highlights:

- Entered into a global neuroscience research & development collaboration with Celgene Corporation to develop new therapies for a broad range of neurodegenerative diseases. The collaboration is focused on three targets implicated in the pathogenesis of several neurodegenerative diseases, including tau, TDP-43 and a third that is undisclosed. Prothena received a \$100 million upfront payment and a \$50 million equity investment by Celgene and is eligible to receive future potential exercise payments and regulatory and commercial milestones for each licensed program. Prothena is also eligible to receive additional royalties on net sales of any resulting marketed products.
 - Presented a broad range of scientific and health outcomes data in oral and poster presentations at the 16th International Symposium on Amyloidosis (ISA). New research was presented at ISA relating to PRX004 for the potential treatment of ATTR amyloidosis, including a proprietary mis-TTR assay developed to measure the misfolded forms of transthyretin (TTR) protein present in plasma of patients with hereditary ATTR amyloidosis, as well as preclinical research demonstrating that conformation-specific antibodies target misfolded TTR and induce immune mediated clearance through phagocytosis.
 - Announced the discontinuation of development of NEOD001, an investigational antibody that was being evaluated for the treatment of AL amyloidosis. The decision was based on results from the Phase 2b PRONTO study and a futility analysis of the Phase 3 VITAL study.
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- Achieved first-in-human dosing in a Phase 1 clinical study of PRX004 in patients with ATTR amyloidosis. PRX004 is an investigational antibody designed to target and clear the pathogenic, misfolded forms of the TTR protein found in ATTR amyloidosis without affecting the native, or normal tetrameric form of the protein. The Phase 1 study will evaluate PRX004 in patients with ATTR amyloidosis to inform possible future studies and will include the use of Prothena's proprietary mis-TTR assay as a pharmacodynamic measure of the levels of misfolded TTR species in plasma across multiple hereditary TTR mutations.

Upcoming Research and Development Milestones

PRX002/RG7935

- The Phase 2 PASADENA study, initiated in the second quarter of 2017, continues to enroll patients with early Parkinson's disease

PRX004

- The Phase 1 study of PRX004, initiated in the second quarter of 2018, continues to enroll patients with ATTR amyloidosis, and preliminary data from this study is expected in 2019

First Quarter 2018 Financial Results and Updated 2018 Financial Guidance

Prothena reported a net loss of \$48.7 million for the first quarter of 2018, as compared to a net loss of \$35.4 million for the first quarter of 2017. Net loss per share for the first quarter of 2018 was \$1.26, as compared to a net loss per share of \$0.99 for the first quarter of 2017.

Prothena reported total revenue of \$0.2 million for the first quarter of 2018, as compared to total revenue of \$0.3 million for the first quarter of 2017 from our collaboration with Roche.

Research and development (R&D) expenses totaled \$34.7 million for the first quarter of 2018, as compared to \$25.7 million for the first quarter of 2017. The increase in R&D expenses for the first quarter of 2018 compared to the same period in the prior year was primarily due to higher consulting expenses, higher personnel costs, higher expense associated with PRX002/RG7935 and to a lesser extent higher clinical trial costs partially offset by lower product manufacturing expenses. R&D expenses included non-cash share-based compensation expense of \$2.3 million for the first quarter of 2018, as compared to \$2.3 million for the first quarter of 2017.

General and administrative (G&A) expenses totaled \$14.2 million for the first quarter of 2018, as compared to \$10.8 million for the first quarter of 2017. The increase in G&A expenses for the first quarter of 2018 compared to the same period in the prior year was primarily due to higher personnel costs and to a lesser extent higher legal expense. G&A expenses included non-cash share-based compensation expense of \$4.6 million in the first quarter of 2018, as compared to \$3.3 million in the first quarter of 2017.

Total non-cash share-based compensation expense was \$6.9 million for the first quarter of 2018, as compared to \$5.6 million for the first quarter of 2017.

As of March 31, 2018, Prothena had \$433.1 million in cash, cash equivalents and restricted cash and no debt.

As of April 20, 2018, Prothena had approximately 39.8 million ordinary shares outstanding.

With the recent discontinuation of the NEOD001 program, the Company is assessing its resources relative to its current pipeline and is developing a reorganization plan. It expects to provide an update during the second quarter on reorganization plans and financial guidance for 2018.

About Prothena

Prothena Corporation plc is a global clinical-stage biotechnology company focused on the discovery and development of novel 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 progressive, life-threatening diseases associated with this biology. Prothena is advancing a pipeline of antibody therapeutic candidates for a number of indications and novel targets including Parkinson's disease and other related synucleinopathies (PRX002/RG7935) and ATTR amyloidosis (PRX004), as well as tau, A β (Amyloid beta) 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 @ProthenaCorp.

Forward-looking Statements

This press release contains forward-looking statements. These statements relate to, among other things, the sufficiency of our cash to support advancement of our R&D pipeline through key milestones; our goal of moving several programs in our clinical and discovery pipeline forward, including those under our collaboration with Celgene; amounts we might receive under our collaboration with Celgene; our focus on pursuing new and better treatment options for patients; the design, proposed mechanism of action and potential therapeutic benefits of PRX004; the objective and design of the Phase 1 study of PRX004; the intended use of our proprietary assay as a pharmacodynamic measure across multiple hereditary TTR mutations; the expected timing of having data from the Phase 1 study of PRX004; the possibility of further studies of PRX004; enrollment in the Phase 2 study of PRX002; and our plan and timing to develop a reorganization plan and provide an update on that plan and financial guidance for 2018. 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) on February 26, 2018 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,	
	2018	2017
Collaboration revenue	\$ 227	\$ 259
Total revenue	227	259
Operating expenses:		
Research and development	34,706	25,698
General and administrative	14,229	10,832
Total operating expenses	48,935	36,530
Loss from operations	(48,708)	(36,271)
Other expense, net	(72)	(774)
Loss before income taxes	(48,780)	(37,045)
Benefit from income taxes	(37)	(1,661)
Net loss	\$ (48,743)	\$ (35,384)
Basic and diluted net loss per share	\$ (1.26)	\$ (0.99)
Shares used to compute basic and diluted net loss per share	38,684	35,758

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

	March 31,	December 31,
	2018	2017
Assets		
Cash and cash equivalents	\$ 429,039	\$ 417,620
Accounts receivable	100,012	240
Other current assets	8,102	8,467
Total current assets	537,153	426,327
Property and equipment, net	54,278	54,990
Restricted cash	4,056	4,056
Other assets	11,160	10,956
Total non-current assets	69,494	70,002
Total assets	\$ 606,647	\$ 496,329
Liabilities and Shareholders' Equity		
Accrued research and development	\$ 15,693	\$ 13,509
Other current liabilities	19,862	23,862
Total current liabilities	35,555	37,371
Deferred revenue	110,242	—
Other non-current liabilities	51,345	51,769
Total non-current liabilities	161,587	51,769
Total liabilities	197,142	89,140
Total shareholders' equity	409,505	407,189
Total liabilities and shareholders' equity	\$ 606,647	\$ 496,329

Media and Investor Contact:

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