

PROTHENA CORP PLC

FORM 8-K (Current report filing)

Filed 05/09/17 for the Period Ending 05/09/17

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 9, 2017

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 9, 2017 , Prothena Corporation plc issued a press release announcing its financial results for the first quarter ended March 31, 2017 . 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 9, 2017.

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 9, 2017

PROTHENA CORPORATION PLC

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



Prothena Reports First Quarter 2017 Financial Results and Provides R&D Update

- **Net cash used in operating and investing activities was \$40.2 million in the first quarter; quarter-end cash and restricted cash position of \$510.6 million , including net proceeds of \$150.3 million raised through March 2017 public equity offering, provides funding to advance R&D pipeline**
- **Completed enrollment in the Phase 2b PRONTO study evaluating NEOD001 in previously treated patients with AL amyloidosis and persistent cardiac dysfunction**
- **Presented results from the Phase 1b study of PRX002/RG7935 in an oral session at the 13th International Conference on Alzheimer’s and Parkinson’s Disease (AD/PD)**

DUBLIN, Ireland - May 9, 2017 - Prothena Corporation plc (NASDAQ:PRTA), a late-stage clinical biotechnology company focused on the discovery, development and commercialization of novel protein immunotherapies, today reported financial results for the first quarter of 2017. In addition, the Company provided an update on its R&D programs.

“Enrollment is now complete in our Phase 2b PRONTO study evaluating NEOD001 for the potential treatment of AL amyloidosis and we expect topline results from this study in the second quarter of 2018,” said Gene Kinney, PhD, President and Chief Executive Officer of Prothena. “Later this month, we also expect to meet an important milestone by completing over-enrollment of our Phase 3 VITAL Amyloidosis Study evaluating NEOD001 in newly diagnosed, treatment naïve patients with AL amyloidosis and cardiac dysfunction. Our balance sheet enables us to progress our clinical programs through key milestones and we are steadily advancing a diverse pipeline of protein immunotherapies across multiple therapeutic categories while strengthening our organization to plan for commercialization of our lead program, NEOD001.”

First Quarter 2017 and Recent Highlights:

- Completed enrollment in the Phase 2b PRONTO study evaluating NEOD001 in previously treated patients with AL amyloidosis and persistent cardiac dysfunction. Based on the high level of patient interest, there are 129 patients randomized in the study, representing over-enrollment by 29 patients. The PRONTO study is a global, double-blind, placebo-controlled, registration-directed study with a primary endpoint of best response over 12 months of the cardiac functional biomarker NT-proBNP, defined by the consensus criteria of NT-proBNP change. Secondary endpoints include quality of life, functional and biomarker measures.
- Expect to complete over-enrollment by mid-May in our Phase 3 VITAL Amyloidosis Study evaluating NEOD001 in newly diagnosed, treatment naïve patients with AL amyloidosis and cardiac dysfunction. The original target enrollment of 236 patients has been met, and patients who are currently in screening have an opportunity to complete this process and based on their eligibility will be randomized into the study. The study will therefore be over-enrolled, with the last patient randomized in the coming weeks. The VITAL study is a global, double-blind, placebo-controlled, registration study with an

event-based composite primary endpoint of all-cause mortality or cardiac hospitalizations as qualifying events. Secondary endpoints include biomarker, quality of life and functional measures.

- In a late-breaking therapeutic strategies session at the 13th International Conference on Alzheimer's and Parkinson's Diseases (AD/PD), Dr. Joseph Jankovic of Baylor College of Medicine [presented](#) clinical data from the 80-patient Phase 1b multiple ascending dose study of PRX002/RG7935 in patients with Parkinson's disease. The positive results support advancing PRX002/RG7935 into a Phase 2 study, PASADENA, which is expected to begin in the second quarter of 2017.
- Completed a successful public offering that raised aggregate net proceeds of \$150.3 million through the issuance of 2.7 million ordinary shares in March 2017.

Upcoming Research and Development Milestones

Prothena's pipeline includes four protein immunotherapy programs.

NEOD001 is a monoclonal antibody for the potential treatment of AL amyloidosis:

- Complete enrollment in the Phase 3 [VITAL Amyloidosis Study](#) expected by mid-May 2017
- Topline results in the Phase 2b [PRONTO](#) study expected in the second quarter of 2018

PRX002/RG7935 is a monoclonal antibody for the potential treatment of Parkinson's disease and other related synucleinopathies, and is the primary focus of Prothena's worldwide collaboration with Roche:

- Phase 2 clinical study, [PASADENA](#), expected to begin in the second quarter of 2017

PRX003 is a monoclonal antibody for the potential treatment of inflammatory diseases, including psoriasis and psoriatic arthritis:

- Topline results from the Phase 1b multiple ascending dose, safety and proof-of-biology [study](#) in 32 patients (8 patients per dose-level cohort, randomized 3:1) with psoriasis expected in the third quarter of 2017

PRX004 is a monoclonal antibody for the potential treatment of ATTR amyloidosis :

- Clinical development expected to begin in early 2018

First Quarter 2017 Financial Results and Updated 2017 Financial Guidance

Prothena reported a net loss of \$35.4 million for the first quarter of 2017, as compared to a net loss of \$27.5 million for the first quarter of 2016. Net loss per share for the first quarter of 2017 was \$0.99 , as compared to a net loss per share for the first quarter of 2016 of \$0.81 .

Prothena reported total revenue of \$0.3 million for the first quarter of 2017, as compared to total revenue of \$0.3 million for the first quarter of 2016.

Research and development (R&D) expenses totaled \$25.7 million for the first quarter of 2017, as compared to \$20.5 million for the first quarter of 2016. The increase in R&D expenses for the first quarter of 2017 was primarily due to increased personnel cost, and higher expenses for product manufacturing and clinical trials. R&D expenses included non-cash share-based compensation expense of \$2.3 million for the first quarter of 2017, as compared to \$1.4 million for the first quarter of 2016.

General and administrative (G&A) expenses totaled \$10.8 million for the first quarter of 2017, as compared to \$7.2 million for first quarter of 2016. The increase in G&A expenses for the first quarter of 2017 was primarily due to increases in personnel costs, consulting expense and other expenses, partially offset by a gain recognized from the assignment of our former South San Francisco facility lease. G&A expenses included non-cash share-based compensation expense of \$3.3 million in the first quarter of 2017, as compared to \$2.3 million in the first quarter of 2016.

Total non-cash share-based compensation expense was \$5.6 million for the first quarter of 2017, as compared to \$3.7 million for the first quarter of 2016.

As of March 31, 2017, Prothena had \$510.6 million in cash, cash equivalents and restricted cash, and no debt.

As of April 21, 2017, Prothena had approximately 38.0 million ordinary shares outstanding.

The Company expects the full year 2017 net cash burn from operating and investing activities to be \$160 to \$170 million, including an expected milestone payment from Roche upon initiation of the Phase 2 study of PRX002/RG7935, and to end the year with approximately \$375 million in cash, cash equivalents and restricted cash (mid-point), which has been updated to include the recent \$150.3 million from the March 2017 public equity offering. The estimated full year 2017 net cash burn from operating and investing activities is primarily driven by an estimated net loss of \$177 to \$191 million, which includes an estimated \$26 million of non-cash share-based compensation expense.

Upcoming Investor Conferences

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

- **Bank of America Merrill Lynch 2017 Healthcare Conference** on May 18, 2017 at 8:00 AM PT/11:00 AM ET in Las Vegas, NV
- **UBS 2017 Global Healthcare Conference** on May 23, 2017 at 8:30 AM ET in New York, NY
- **Jefferies 2017 Global Healthcare Conference** on June 8, 2017 at 11:30 AM ET in New York, NY

A live webcast of the presentations can be accessed through the investor relations 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.

About Prothena

Prothena Corporation plc is a global, late-stage clinical biotechnology company establishing fully-integrated research, development and commercial capabilities. Fueled by its deep scientific understanding built over decades of research in protein misfolding and cell adhesion - the root causes of many serious or currently untreatable amyloid and inflammatory diseases - Prothena seeks to fundamentally change the course of progressive diseases associated with this biology. The Company's pipeline of antibody therapeutic candidates targets a number of indications including AL amyloidosis (NEOD001), Parkinson's disease and other related synucleinopathies (PRX002/RG7935), inflammatory diseases, including psoriasis and psoriatic arthritis (PRX003), and ATTR amyloidosis (PRX004). The Company continues discovery of additional novel therapeutic candidates where its deep scientific understanding of disease pathology can be leveraged. For more information, please visit the Company's website at www.prothena.com

Forward-looking Statements

This press release contains forward-looking statements. These statements relate to, among other things, the sufficiency of our cash position to advance our R&D pipeline through key milestones; the timing of completing enrollment in the Phase 3 study and announcing topline results from the Phase 2b study of NEOD001; the timing of initiating a Phase 2 study of PRX002/RG7935; the timing of announcing topline results from the Phase 1b study of PRX003; the timing of initiating clinical development of PRX004; our anticipated net cash burn from operating and investing activities for 2017 and expected cash balance at the end of 2017; and our estimated net loss and non-cash share-based compensation expense for 2017. 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 27, 2017 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,	
	2017	2016
Collaboration revenue	\$ 259	\$ 265
Total revenue	259	265
Operating expenses:		
Research and development	25,698	20,493
General and administrative	10,832	7,182
Total operating expenses	36,530	27,675
Loss from operations	(36,271)	(27,410)
Other income (expense), net:	(774)	70
Loss before income taxes	(37,045)	(27,340)
Provision for (benefit from) income taxes	(1,661)	181
Net loss	\$ (35,384)	\$ (27,521)
Basic and diluted net loss per share	\$ (0.99)	\$ (0.81)
Shares used to compute basic and diluted net loss per share	35,758	34,026

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

	March 31,	December 31,
	2017	2016
Assets		
Cash and cash equivalents	\$ 506,550	\$ 386,923
Other current assets	7,654	4,439
Total current assets	514,204	391,362
Property and equipment, net	56,084	56,452
Restricted cash	4,056	4,056
Other assets	7,606	8,106
Total non-current assets	67,746	68,614
Total assets	\$ 581,950	\$ 459,976
Liabilities and Shareholders' Equity		
Accrued research and development	\$ 21,710	\$ 19,073
Other current liabilities	11,970	22,002
Total current liabilities	33,680	41,075
Non-current liabilities:	52,022	53,498
Total liabilities	85,702	94,573
Total shareholders' equity	496,248	365,403
Total liabilities and shareholders' equity	\$ 581,950	\$ 459,976

Contacts

Investors: Tran Nguyen, CFO
650-837-8535, IR@prothena.com

Media: Ellen Rose, Head of Communications
650-922-2405, ellen.rose@prothena.com