

PROTHENA CORP PLC

FORM 8-K (Current report filing)

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**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 8, 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 August 8, 2017 , Prothena Corporation plc issued a press release announcing its financial results for the second quarter and six months ended June 30, 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 August 8, 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: August 8, 2017

PROTHENA CORPORATION PLC

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



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

- **Net cash used in operating and investing activities was \$36.3 million in the second quarter and \$76.5 million for the first six months of 2017; quarter-end cash and restricted cash position of \$475.8 million , provides funding to advance diverse pipeline**
- **Initiated, with Roche, the global Phase 2 PASADENA study of PRX002/RG7935 in patients with early Parkinson’s disease, triggering a \$30 million milestone payment from Roche to Prothena**
- **Completed enrollment in the Phase 3 VITAL Amyloidosis Study evaluating NEOD001 in newly diagnosed, treatment naïve patients with AL amyloidosis and cardiac dysfunction**
- **Strengthened management team with appointments of Sarah Noonberg, MD, PhD as Chief Medical Officer and Wagner Zago, PhD as Chief Scientific Officer**

DUBLIN, Ireland - August 8, 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 second quarter and first six months of 2017. In addition, the Company provided an update on its R&D programs.

“During the quarter, we achieved two important milestones in our first-in-class protein immunotherapy pipeline, completing enrollment of our Phase 3 VITAL Amyloidosis Study evaluating NEOD001 in newly diagnosed, treatment naïve patients with AL amyloidosis and cardiac dysfunction, and initiating the Phase 2 PASADENA study of PRX002/RG7935 in patients with early Parkinson’s disease,” said Gene Kinney, PhD, President and Chief Executive Officer of Prothena. “We also appointed two exceptionally talented leaders into key roles to further expand our ability to advance our R&D pipeline. Looking ahead, we expect topline results from our Phase 1b MAD study of PRX003 in patients with psoriasis in October, and topline results from our Phase 2b PRONTO study of NEOD001 in patients with AL amyloidosis in the second quarter of 2018. With both the PRONTO and VITAL studies now fully enrolled, our team is focused on activities to support registration submissions for NEOD001.”

Second Quarter 2017 and Recent Highlights:

- **Initiated the Phase 2 PASADENA study of PRX002/RG7935 in patients with early Parkinson’s disease, triggering a \$30 million milestone payment from Roche to Prothena. PASADENA is a global two-part clinical study that is being conducted by Roche. The primary endpoint of this study is the comparison of change from baseline in the Movement Disorder Society- Unified Parkinson's Disease Rating Scale (MDS-UPDRS) total score (parts 1, 2 and 3) at week 52 in each of the two treatment groups vs. the placebo group.**
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- Completed enrollment in the 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 was exceeded and 260 patients have been randomized into the study. The VITAL study is a global, double-blind, placebo-controlled, registrational 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 supported advancing PRX002/RG7935 into a Phase 2 study, PASADENA.
- Appointed Sarah Noonberg, MD, PhD as Chief Medical Officer to define and advance Prothena's product pipeline and lead its clinical and medical organizations. Dr. Noonberg has extensive drug development experience across several therapeutic categories and has led large, global organizations across several phases of drug development.
- Appointed Wagner Zago, PhD as Chief Scientific Officer to define and execute Prothena's research strategy and advance its drug discovery pipeline. Dr. Zago had been Prothena's Head of Research since 2015 and has led teams that have advanced four programs based on novel mechanisms into clinical development.

Upcoming Research and Development Milestones

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

- Topline results in the Phase 2b PRONTO study (129 patients) expected in the second quarter of 2018

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 October 2017

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

- Clinical development expected to begin by mid-2018

Second Quarter and First Six Months of 2017 Financial Results

Prothena reported a net loss of \$17.7 million and \$53.1 million for the second quarter and first six months of 2017, respectively, as compared to a net loss of \$40.4 million and \$68.0 million for the second quarter and first six months of 2016, respectively. Net loss per share for the second quarter and first six months of 2017 was \$0.46 and \$1.44, respectively, as compared to a net loss per share of \$1.18 and \$1.99 for the second quarter and first six months of 2016, respectively.

Prothena reported total revenue of \$26.8 million and \$27.1 million for the second quarter and first six months of 2017, respectively, as compared to total revenue of \$0.3 million and \$0.6 million for the second quarter

and first six months of 2016, respectively. The increase in revenue for the second quarter and first six months of 2017 was primarily due to achievement of a clinical milestone from Roche of \$30.0 million (of which \$26.6 million was recognized as collaboration revenue and \$3.4 million was recognized as an offset to R&D expenses).

Research and development (R&D) expenses totaled \$34.0 million and \$59.7 million for the second quarter and first six months of 2017, respectively, as compared to \$32.4 million and \$52.9 million for the second quarter and first six months of 2016, respectively. The increase in R&D expenses for the second quarter and first six months of 2017 was primarily due to higher clinical trial and personnel cost offset in part by lower external expenses for product manufacturing. R&D expenses included non-cash share-based compensation expense of \$2.7 million and \$5.0 million for the second quarter and first six months of 2017, respectively, as compared to \$1.8 million and \$3.2 million for the second quarter and first six months of 2016, respectively.

General and administrative (G&A) expenses totaled \$10.9 million and \$21.7 million for the second quarter and first six months of 2017, respectively, as compared to \$8.1 million and \$15.3 million for second quarter and first six months of 2016, respectively. The increase in G&A expenses for the second quarter was primarily due to increases in personnel costs. The increase in G&A expenses for the first six months was primarily due to increases in personnel, consulting and other expenses partially offset by a gain recognized in the first quarter of 2017 from the assignment of our former South San Francisco facility lease. G&A expenses included non-cash share-based compensation expense of \$3.9 million and \$7.2 million in the second quarter and first six months of 2017, respectively, as compared to \$2.7 million and \$5.0 million in the second quarter and first six six months of 2016, respectively.

Total non-cash share-based compensation expense was \$6.7 million and \$12.3 million for the second quarter and first six months of 2017, respectively, as compared to \$4.5 million and \$8.3 million for the second quarter and first six months of 2016, respectively.

As of June 30, 2017 , Prothena had \$475.8 million in cash, cash equivalents and restricted cash and no debt.

As of July 21, 2017 , Prothena had approximately 38.3 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, which includes the milestone from Roche earned in the second quarter of 2017 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). 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.

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 funding to advance our diverse pipeline; the timing of announcing topline results from the Phase 2b study of NEOD001; the timing of announcing topline results from the Phase 1b study of PRX003; the timing of initiating clinical development of PRX004; our expected net cash burn from operating and investing activities for 2017 and 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Collaboration revenue	\$ 26,812	\$ 333	\$ 27,071	\$ 598
Total revenue	26,812	333	27,071	598
Operating expenses:				
Research and development	34,032	32,359	59,730	52,852
General and administrative	10,912	8,134	21,744	15,316
Total operating expenses	44,944	40,493	81,474	68,168
Loss from operations	(18,132)	(40,160)	(54,403)	(67,570)
Other expense, net	(856)	(96)	(1,630)	(26)
Loss before income taxes	(18,988)	(40,256)	(56,033)	(67,596)
Provision for (benefit from) income taxes	(1,287)	189	(2,948)	370
Net loss	\$ (17,701)	\$ (40,445)	\$ (53,085)	\$ (67,966)
Basic and diluted net loss per share	\$ (0.46)	\$ (1.18)	\$ (1.44)	\$ (1.99)
Shares used to compute basic and diluted net loss per share	38,073	34,358	36,922	34,192

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

	June 30,	December 31,
	2017	2016
Assets		
Cash and cash equivalents	\$ 471,729	\$ 386,923
Other current assets	39,991	4,439
Total current assets	511,720	391,362
Property and equipment, net	55,843	56,452
Restricted cash	4,056	4,056
Other assets	7,381	8,106
Total non-current assets	67,280	68,614
Total assets	<u>\$ 579,000</u>	<u>\$ 459,976</u>
Liabilities and Shareholders' Equity		
Accrued research and development	\$ 20,799	\$ 19,073
Other current liabilities	18,800	22,002
Total current liabilities	39,599	41,075
Non-current liabilities:	52,425	53,498
Total liabilities	92,024	94,573
Total shareholders' equity	486,976	365,403
Total liabilities and shareholders' equity	<u>\$ 579,000</u>	<u>\$ 459,976</u>

Media & Investor Contact:

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