

**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): November 4, 2020

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.)

**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 November 4, 2020, Prothena Corporation plc issued a press release announcing its financial results for the third quarter ended September 30, 2020. 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 November 4, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: November 4, 2020

PROTHENA CORPORATION PLC

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



Prothena Reports Third Quarter 2020 Financial Results and Provides R&D Update

- **Net cash used in operating and investing activities was \$19.5 million in the third quarter and \$61.4 million for the first nine months of 2020; quarter-end cash and restricted cash position of \$317.2 million provides funding to advance the R&D pipeline**
- **Roche presented results from the Phase 2 PASADENA study of prasinezumab in patients with early Parkinson's disease in an oral top abstract presentation at MDS Congress 2020**
- **Announced that Roche and Prothena will advance prasinezumab into late-stage clinical development**
- **Presented new preclinical data from two Alzheimer's disease programs at CTAD 2020**

DUBLIN, Ireland, November 4, 2020 -- Prothena Corporation plc (NASDAQ:PRTA), a late-stage clinical company with expertise in protein dysregulation and a diverse pipeline of investigational therapeutics for neurodegenerative and rare peripheral amyloid diseases, today reported financial results for the third quarter and first nine months of 2020. In addition, the Company provided an update on its R&D programs.

"During the third quarter, Roche presented data from the Phase 2 PASADENA study of prasinezumab in patients with early Parkinson's disease that demonstrated signals of efficacy consistent with disease modification and recently, we announced that prasinezumab will advance into a late-stage study," said Gene Kinney, Ph.D., President and Chief Executive Officer of Prothena. "Moving into the fourth quarter, we are building on this momentum with two new data presentations from our Alzheimer's disease portfolio at CTAD 2020 this week and additional data from our Phase 1 study of PRX004 in ATTR amyloidosis is expected later this quarter. Looking ahead, we remain focused on advancing our R&D pipeline towards key milestones."

Third Quarter and Recent Highlights

- **Announced results from the Phase 2 PASADENA study of prasinezumab in patients with early Parkinson's disease that were presented by Roche at the International Parkinson and Movement Disorder Society's MDS Virtual Congress 2020 (MDS Congress 2020) on September 15, 2020. Prasinezumab is the first potentially disease-modifying, anti-alpha-synuclein antibody to demonstrate signs of efficacy on multiple pre-specified secondary and exploratory clinical endpoints in patients with early Parkinson's disease. In the study, prasinezumab significantly reduced decline in motor function by 35% (pooled dose levels) vs. placebo after one year of treatment on the centrally rated assessment of Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part III, a clinical examination of motor function. Prasinezumab-treated patients also demonstrated a significant delay in time to clinically meaningful worsening of motor progression on the site rated assessment of time to at least a 5-point progression on MDS-UPDRS Part III vs. placebo over one year, with a hazard ratio of 0.82 (pooled dose levels).**

- Announced that Roche and Prothena will advance prasinezumab into a late-stage (Phase 2b) study in patients with early Parkinson's disease. The study will be designed to further assess the efficacy of prasinezumab by expanding upon the patient population enrolled in PASADENA to include patients with early Parkinson's disease on stable levodopa therapy.
- Presented preclinical data from two programs in its Alzheimer's disease portfolio at the 13th Clinical Trials on Alzheimer's Disease Conference 2020 (CTAD 2020). First, a next generation anti- A β antibody, PRX012, for more convenient subcutaneous administration to improve patient access. Second, a multi-immunogen vaccine that targets both A β and Tau, two main pathological hallmarks of Alzheimer's disease, for the prevention and treatment of Alzheimer's disease.

Upcoming Research and Development Milestones

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

- Part 2 of the Phase 2 PASADENA study (a 52-week blinded extension phase) is ongoing.
- Prothena will earn a \$60 million clinical milestone payment upon the first patient dosed in the Phase 2b study. Further details are expected to be announced in the first half of 2021.

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

- Prothena expects to report new data in fourth quarter of this year from the dose-escalation and available LTE portion of the study.
- Prothena continues to believe that the study has advanced sufficiently to determine next steps for the program and has begun further clinical development planning for next clinical studies in patients with moderate-to-advanced ATTR cardiomyopathy (ATTR-CM). Current therapies have not demonstrated efficacy in these patients who are at high risk of early mortality.

Discovery and Preclinical Development: Prothena is advancing an early-stage pipeline of programs for a number of potential neurological indications

- Prothena continues to expect to advance IND-enabling activities in 2020 for PRX005, our preclinical tau program, part of a global neuroscience collaboration with Bristol-Myers Squibb, and expects to file an IND in 2021.
- Prothena has initiated IND-enabling studies for PRX012, our preclinical A β program, and expects to file an IND in 2021.

Upcoming Investor Conferences

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

- Stifel 2020 Virtual Healthcare Conference on Tuesday November 17, 2020 at 4:00 PM Eastern Time
- Jefferies Virtual London Healthcare Conference on Thursday November 19, 2020 at 2:55 PM Eastern Time

A live webcast of the presentations can be accessed through the Investors 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.

Third Quarter and First Nine Months of 2020 Financial Results

For the third quarter and first nine months of 2020, Prothena reported a net loss of \$30.6 million and \$80.4 million, respectively, as compared to a net loss of \$19.4 million and \$56.1 million for the third quarter and first nine months of 2019, respectively. The third quarter and first nine months of 2019 included a restructuring credit of nil and \$0.1 million, respectively, which resulted from an adjustment in previously recorded employee termination benefits associated with the discontinuation of the NEOD001 program. Net loss per share for the third quarter and first nine months of 2020 was \$0.77 and \$2.02, respectively, as compared to a net loss per share of \$0.49 and \$1.41 for the third quarter and first nine months of 2019, respectively.

Prothena reported total revenue, primarily from its collaboration with Roche, of \$0.2 million and \$0.5 million for the third quarter and first nine months of 2020, respectively as compared to total revenue of \$0.2 million and \$0.6 million for the third quarter and first nine months of 2019, respectively.

Research and development (R&D) expenses totaled \$21.6 million and \$54.1 million for the third quarter and first nine months of 2020, respectively, as compared to \$12.5 million and \$35.4 million for the third quarter and first nine months of 2019, respectively. The increase in R&D expense for the third quarter and first nine months of 2020 compared to the same periods in the prior year was primarily due to higher manufacturing costs, higher collaboration expense with Roche related to the prasinezumab program and higher R&D consulting expense. R&D expenses included non-cash share-based compensation expense of \$2.1 million and \$6.2 million for the third quarter and first nine months of 2020, respectively, as compared to \$2.0 million and \$6.2 million for the third quarter and first nine months of 2019, respectively.

General and administrative (G&A) expenses totaled \$9.4 million and \$28.8 million for the third quarter and first nine months of 2020, respectively, as compared to \$8.7 million and \$27.7 million for the third quarter and first nine months of 2019, respectively. The increase in G&A expenses for the third quarter and first nine months of 2020 compared to the same periods in the prior year was primarily related to higher costs for our director and officer insurance premiums offset in part by lower share-based compensation expense. G&A expenses included non-cash share-based compensation expense of \$3.5 million and \$10.6 million for the third quarter and first nine months of 2020, respectively, as compared to \$3.9 million and \$12.1 million for the third quarter and first nine months of 2019, respectively.

Total non-cash share-based compensation expense was \$5.6 million and \$16.8 million for the third quarter and first nine months of 2020, respectively, as compared to \$5.8 million and \$18.3 million for the third quarter and first nine months of 2019, respectively.

As of September 30, 2020, Prothena had \$317.2 million in cash, cash equivalents and restricted cash and no debt.

As of October 30, 2020, Prothena had approximately 39.9 million ordinary shares outstanding.

The Company continues to expect its full year 2020 net cash burn from operating and investing activities to be \$75-\$85 million, and expects to end the year with approximately \$299 million in cash, cash equivalents and restricted cash (midpoint). The estimated full year 2020 net cash burn from operating and investing activities is primarily driven by estimated net loss of \$101-\$118 million, which includes an estimated \$23 million of non-cash share-based compensation expense.

Inducement Grant Under NASDAQ Listing Rule 5635(C)(4)

In connection with hiring two new employees, the compensation committee of the Company's board of directors granted the individuals hired by the Company, in the aggregate, options to purchase 90,000 ordinary shares of the Company. The options have an exercise price per share equal to \$11.03, which was the closing trading price on November 2, 2020, the date of the grants. The inducement awards will vest over four years, with 25% of the underlying shares vesting on the one-year anniversary of the date of grants and 1/48th of the underlying shares vesting monthly thereafter over 36 months. The options were granted pursuant to the Company's 2020 Employment Inducement Incentive Plan, which was approved by the Company's board of directors under Rule 5635(c)(4) of The Nasdaq Global Market for equity grants to induce new employees to enter into employment with the Company.

About Prothena

Prothena Corporation plc is a late-stage clinical company with expertise in protein dysregulation and a diverse pipeline of novel investigational therapeutics with the potential to change the course of devastating neurodegenerative and rare peripheral amyloid diseases. Fueled by its deep scientific expertise built over decades of research, Prothena is advancing a pipeline of therapeutic candidates for a number of indications and novel targets for which its ability to integrate scientific insights around neurological dysfunction and the biology of misfolded proteins can be leveraged. Prothena's partnered programs include prasinezumab (PRX002/RG7935), in collaboration with Roche for the potential treatment of Parkinson's disease and other related synucleinopathies, and programs that target tau (PRX005), TDP-43, and an undisclosed target in collaboration with Bristol-Myers Squibb for the potential treatment of Alzheimer's disease, amyotrophic lateral sclerosis (ALS), frontotemporal dementia (FTD) or other neurodegenerative diseases. Prothena's proprietary programs include PRX004 for the potential treatment of ATTR amyloidosis, and a portfolio of programs for the potential treatment of Alzheimer's disease including PRX012 that targets A β (Amyloid beta). For more information, please visit the Company's website at www.prothena.com and follow the Company on Twitter @ProthenaCorp.

Forward-looking Statements

This press release contains forward-looking statements. These statements relate to, among other things, the sufficiency of our cash position to fund advancement of a broad pipeline; the treatment potential and proposed mechanisms of action of prasinezumab, PRX004, PRX005 and PRX012; plans for the ongoing Phase 2 clinical study of prasinezumab and the Phase 1 clinical study of PRX004; the expected timing of reporting data from the Phase 1 clinical study of PRX004; plans for future clinical studies of prasinezumab and PRX004; amounts we might receive under our collaboration with Roche; the continued advancement of our discovery and preclinical pipeline; the timing of IND-enabling activities from our tau and A β programs; our anticipated net cash burn from operating and investing activities for 2020 and expected cash balance at the end of 2020; and our estimated net loss and non-cash share-based compensation expense for 2020. 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 effects on our business of the worldwide COVID-19 pandemic and 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 March 3, 2020, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings 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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Collaboration revenue	\$ 157	\$ 205	\$ 443	\$ 558
License revenue	—	—	50	—
Total revenue	157	205	493	558
Operating expenses:				
Research and development	21,605	12,486	54,124	35,365
General and administrative	9,398	8,691	28,795	27,677
Restructuring credits	—	—	—	(61)
Total operating expenses	31,003	21,177	82,919	62,981
Loss from operations	(30,846)	(20,972)	(82,426)	(62,423)
Other income, net	54	1,992	1,362	6,810
Loss before income taxes	(30,792)	(18,980)	(81,064)	(55,613)
Provision for (benefit from) income taxes	(215)	468	(636)	510
Net loss	\$ (30,577)	\$ (19,448)	\$ (80,428)	\$ (56,123)
Basic and diluted net loss per share	\$ (0.77)	\$ (0.49)	\$ (2.02)	\$ (1.41)
Shares used to compute basic and diluted net loss per share	39,917	39,897	39,912	39,877

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

	September 30, 2020	December 31, 2019
Assets		
Cash and cash equivalents	\$ 314,525	\$ 375,723
Accounts receivable	22	68
Prepaid expenses and other current assets	4,586	2,584
Restricted cash, current	1,352	—
Total current assets	320,485	378,375
Property and equipment, net	2,899	3,874
Operating lease right-of-use assets	19,197	23,274
Restricted cash, non-current	1,352	2,704
Other non-current assets	11,851	11,041
Total non-current assets	35,299	40,893
Total assets	\$ 355,784	\$ 419,268
Liabilities and Shareholders' Equity		
Accrued research and development	\$ 7,617	\$ 5,826
Lease liability, current	5,408	5,101
Other current liabilities	8,697	6,787
Total current liabilities	21,722	17,714
Deferred revenue, non current	110,242	110,242
Lease liability, non-current	13,753	17,838
Other non-current liabilities	553	553
Total non-current liabilities	124,548	128,633
Total liabilities	146,270	146,347
Total shareholders' equity	209,514	272,921
Total liabilities and shareholders' equity	\$ 355,784	\$ 419,268

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Investors

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