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): April 18, 2019

PROTHENA CORPORATION PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	**001-35676**	**98-1111119**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o 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 o

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. o

Item 8.01 Other Events.

On April 18, 2019, Prothena Corporation plc issued a press release announcing results from the Phase 3 VITAL Amyloidosis Study of NEOD001. That press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press release dated April 18, 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: April 18, 2019

PROTHENA CORPORATION PLC

By: /s/ Tran B. Nguyen

Name: Tran B. Nguyen

Title: Chief Operating Officer and Chief Financial Officer

Exhibit 99.1

Prothena Reports Results from the Phase 3 VITAL Amyloidosis Study of NEOD001 (birtamimab) in AL Amyloidosis

- **Results from final analysis of the composite primary endpoint were consistent with the futility analysis reported in April 2018**
- **Results from post hoc analyses revealed a potential survival benefit with NEOD001 in the category of patients at the highest risk for early mortality (Mayo Stage IV)**
- **Exploring potential business development opportunities to advance NEOD001**
- **Investor conference call and webcast scheduled today at 4:30PM ET**

DUBLIN, Ireland, April 18, 2019 -- Prothena Corporation plc (NASDAQ:PRTA), a clinical-stage neuroscience company, today reported final 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=0.3300) 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).

“We are grateful to patients, their families, investigators and study site staff who made this study, and what we have learned, possible,” said Gene Kinney, Ph.D., President and Chief Executive Officer of Prothena. “Following discontinuation of the VITAL study, we analyzed the results in order to contribute to the body of knowledge about AL amyloidosis with data from this first randomized, placebo-controlled Phase 3 study of an amyloid targeting agent on top of standard of care chemotherapy. These post hoc analyses suggest that in the category of patients at highest risk for early mortality, NEOD001 has the potential to provide a survival benefit on top of standard of care. We are therefore exploring potential business development opportunities that could result in further clinical investigation of NEOD001.”

Phase 3 VITAL Study Results

The Phase 3 VITAL study (N=260) was terminated early based on a futility analysis conducted in April 2018 with a HR of 0.84 favoring NEOD001 on top of standard of care versus placebo on top of standard of care. The final 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) was 0.835 (95% CI: 0.5799, 1.2011; p=0.3300). This final HR was consistent with the futility analysis reported in April 2018, further supporting that the study, as designed, would not have met its primary endpoint. None of the secondary endpoints achieved statistical significance in the total study population.

Baseline demographics and characteristics were well-balanced across the NEOD001 and control arms of the study. NEOD001 was generally safe and well tolerated. The NEOD001 and control arms had similar frequencies of treatment emergent adverse events (TEAEs, 98 percent and 100 percent, respectively) and serious adverse events (SAEs, 68 percent and 70 percent, respectively).

The most common TEAEs were fatigue, nausea, peripheral edema, constipation and diarrhea, and were similar in both arms. Of the patients with a serious adverse event, 95 percent were considered not related to NEOD001.

Post Hoc Analyses

Post hoc analyses by their nature have an increased potential for type 1 error, meaning there is an increased potential for a false positive finding.

Study termination by sponsor was the primary reason for patient discontinuation, and nearly all (94 percent) occurred after the initial 12 months. Therefore, the initial 12-month study period, because it had the least censoring, was the basis of the modified intent-to-treat (mITT) analyses.

The final hazard ratios, which favored NEOD001 for the composite primary endpoint, were largely attributable to all-cause mortality rather than cardiac hospitalization in both the intent-to-treat (ITT) and mITT analyses.

Further evaluations included analyses by Mayo Staging, which is a prognostic categorization system for mortality risk in newly diagnosed patients. Mayo Staging was utilized as a randomization stratification factor in the Phase 3 VITAL study. Patients in Mayo Stage IV are at highest risk for early mortality (Kumar et al., 2012), and represented approximately 30 percent of the patients enrolled in the Phase 3 VITAL study (n=77 of 260).

The mITT analyses of time to all-cause mortality by Mayo Stage revealed a potential survival benefit favoring NEOD001 for those patients categorized as Mayo Stage IV, with a hazard ratio of 0.498 (95% CI: 0.2404, 1.0304; p=0.0556). The safety profile of NEOD001 within Mayo Stage IV was consistent with the overall study population.

The majority (84 percent) of mortality events in the study occurred in the initial 12 months, and of these, approximately half were in Mayo Stage IV. In the mITT analyses, the median overall survival was not reached (>12 months) in the control arms of Mayo Stages I, II or III and was only reached in the control arm of Mayo Stage IV (8.3 months). In the mITT analyses of the NEOD001 treatment arm, the median overall survival was not reached (>12 months) for any Mayo Stage population, including Mayo Stage IV.

ITT and mITT (Initial 12-Month Study Period) Results:

Mayo Stage (N)	**Endpoint[1,2]**	**ITT analyses HR[4] (95%CI) p-value[5]**	**mITT analyses[3] HR[4] (95%CI) p-value[5]**
All (N=260)	Composite primary endpoint	0.835 (0.5799, 1.2011) p=0.3300	0.784 (0.5341, 1.1507) p=0.2129
Stage I-III (n=183)	All-cause mortality	1.334 (0.7386, 2.4107) p=0.3375	1.244 (0.6435, 2.4035) p=0.5159
Stage IV (n=77)	All-cause mortality	0.544 (0.2738, 1.0826) p=0.0787	0.498 (0.2404, 1.0304) p=0.0556

[1]Composite primary endpoint is time to all-cause mortality or time to cardiac hospitalization more than 90 days after first infusion of study drug
[2]All-cause mortality regardless of prior cardiac hospitalization
[3]mITT = initial 12-month study period
[4]HR < 1.0 favors NEOD001 + SOC / HR > 1.0 favors placebo + SOC
[5]All p-values other than for the composite primary endpoint for the ITT analysis, are descriptive

Phase 3 VITAL Study Design

The VITAL Amyloidosis Study was a Phase 3 global, multi-center, randomized, double-blind, placebo-controlled clinical study of NEOD001. The study enrolled 260 newly diagnosed, treatment-naïve patients with AL amyloidosis and cardiac dysfunction. Patients were randomized on a 1:1 basis to receive 24 mg/kg of NEOD001 or placebo via intravenous infusion every 28 days, with both arms receiving concurrent standard of care chemotherapy consisting of a first-line bortezomib-containing regimen. Randomization stratification factors were Mayo Stage, renal stage and 6-Minute Walk Distance. The composite primary endpoint was event-based, with time to all-cause mortality or time to cardiac hospitalizations more than 90 days after first infusion of study drug counted as events. Key secondary endpoints were Short Form-36v2 Physical Component Summary Score, 6-Minute Walk Distance and cardiac response (NT-proBNP best response).

Prothena plans to present results from this study at an upcoming scientific conference.

Conference Call Details

Prothena management will discuss results of the Phase 3 VITAL study during a live audio webcast and conference call today, April 18, 2019, at 4:30 PM ET. The webcast will be made available on the Company's website at www.prothena.com under the Investors tab in the Events and Presentations section. Following the live audio webcast, a replay will be available on the Company's website for at least 90 days.

To access the call via dial-in, please dial (877) 887-5215 (U.S. and Canada toll free) or (315) 625-3069 (international) five minutes prior to the start time and refer to conference ID number 8384875. A replay of the call will be available until May 2, 2019 date via dial-in at (855) 859-2056 (U.S. and Canada toll free) or (404) 537-3406 (international), Conference ID Number 8384875.

About NEOD001 (birtamimab)

NEOD001 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. Preclinical research has shown that NEOD001 binds to both soluble and insoluble aggregated kappa and lambda light chains and recognizes an epitope that is exposed at the earliest stages of abnormal light chain misfolding through aggregation of deposited amyloid involved in AL amyloidosis. Birtamimab has recently been listed as the recommended international nonproprietary name (INN) for NEOD001.

About AL Amyloidosis

Systemic amyloidoses are a complex group of diseases caused by tissue deposition of misfolded proteins that result in progressive organ damage. AL amyloidosis, the most common type, is a rare, progressive, and typically fatal disease caused by extracellular deposition of misfolded immunoglobulin light chains. An excess of light chains prone to misfolding are produced by clonal plasma cells. Soluble toxic aggregates and deposited fibrils (amyloid) lead to progressive failure of vital organs including the heart, kidneys and nervous system, causing significant morbidity and mortality. It is estimated that approximately 30,000 - 45,000 patients in the U.S. and Europe suffer from this disease. There are no approved treatments for AL amyloidosis, although patients may be treated off-label with therapies (including chemotherapeutic approaches) directed at the plasma cell dyscrasia. There is a large unmet need for therapies that improve survival and quality of life. For more information on AL amyloidosis, please visit the websites of the Amyloidosis Support Groups, The Amyloidosis Research Consortium, and the Amyloidosis Foundation.

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 results from post hoc analyses that reveal a potential survival benefit of NEOD001 in the category of patients with the highest risk of early mortality (Mayo Stage IV); our exploration of potential business development opportunities that could result in further clinical investigation of NEOD001; the design and proposed mechanisms of action of NEOD001; and our plan to present the Phase 3 VITAL study results at an upcoming medical conference. 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.

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