Prothena Reports First Quarter 2022 Financial Results and Business Highlights

5/5/2022

- Net cash used in operating and investing activities was $37.4 million in the first quarter; quarter-end cash and restricted cash position was $544.3 million
- Advanced PRX012, a potential best-in-class, subcutaneous treatment for Alzheimer's disease, into a Phase 1 clinical study and received FDA Fast Track designation
- Multiple presentations at AD/PD 2022 highlighting depth of neurodegenerative portfolio targeting Alzheimer's and Parkinson's diseases

DUBLIN, Ireland, May 05, 2022 (GLOBE NEWSWIRE) -- Prothena Corporation plc (NASDAQ:PRTA), a late-stage clinical biotechnology company with a robust pipeline of investigational therapeutics built on protein dysregulation expertise, today reported financial results for the first quarter 2022.

"We are excited to kick off 2022 with a strong first quarter, further reinforcing continued execution across our portfolio. We remain focused on the Phase 3 AFFIRM-AL trial of birtamimab being conducted under a SPA agreement with FDA. We also achieved multiple milestones in our PRX012 program, our next-generation, subcutaneous anti-amyloid beta antibody, having received FDA clearance of the IND, initiated a Phase 1 clinical study and received Fast Track designation from FDA. Additionally, we presented positive preclinical findings for our Alzheimer's and Parkinson's active vaccine candidates at AD/PD 2022, further highlighting the depth of our neurodegenerative pipeline," said Gene Kinney, Ph.D., President and Chief Executive Officer of Prothena. "Later this year, we look forward to clinical data from our PRX005 Phase 1 study and the initiation of a Phase 1 multiple ascending dose study for PRX012. We will continue to drive meaningful growth this year across our portfolio and our strong capital position supports our leadership in protein dysregulation."

First Quarter and Recent Business Highlights and Upcoming Milestones

Neurodegenerative Diseases Portfolio

Alzheimer's Disease (AD)

PRX012, a potential best-in-class treatment for AD, is an investigational monoclonal antibody targeting a key epitope at the N-terminus of amyloid beta (Aβ) with high binding potency supporting subcutaneous administration

- Received U.S. Food and Drug Administration (FDA) clearance of the Investigational New Drug (IND) application
- Received Fast Track designation for PRX012 from FDA for the treatment of AD
- Initiated Phase 1 single ascending dose (SAD) study, a randomized, double-blind, placebo-controlled study to evaluate safety, tolerability, immunogenicity, and pharmacokinetics in healthy volunteers and patients with Alzheimer's disease
- Phase 1 multiple ascending dose (MAD) study initiation expected by year-end 2022
- Topline Phase 1 data expected in 2023

PRX005, a potential best-in-class treatment for AD, is an investigational antibody that specifically targets a key epitope within the microtubule binding region (MTBR) of tau, a protein implicated in diseases including AD, frontotemporal dementia (FTD), progressive supranuclear palsy (PSP), chronic traumatic encephalopathy (CTE), and other tauopathies. PRX005 is part of the global neuroscience research and development collaboration with Bristol Myers Squibb

- Topline Phase 1 data expected in 2022

Dual Aβ /tau vaccine, a potential first-in-class treatment and prevention therapy for AD, is a dual-target vaccine targeting key epitopes within the Aβ and tau proteins to promote amyloid clearance and blockade of pathogenic tau

- Oral presentation on preclinical data at the International Conference on Alzheimer's and Parkinson's Diseases (AD/PD 2022) in March demonstrating that Prothena's dual Aβ/tau vaccine generated anti-Aβ and anti-tau antibodies to enable phagocytosis of Aβ and to neutralize tau
- IND filing expected in 2023

Parkinson's Disease (PD)

Prasinezumab, a potential first-in-class treatment for PD, is a humanized monoclonal antibody designed to target key epitopes within the C-terminus of alpha-synuclein and is the focus of the worldwide collaboration with Roche

- Oral presentation by partner Roche at AD/PD 2022 on the Phase 2 PASADENA study of prasinezumab, further supports a potential effect on delaying motor progression in patients

- Phase 2b PADOVA study results expected in 2024

Rare Peripheral Amyloid Diseases Portfolio

AL Amyloidosis

Birtamimab, a potential best-in-class amyloid depleter treatment for AL amyloidosis, is an investigational humanized monoclonal antibody designed to directly neutralize soluble toxic aggregates and promote clearance of amyloid that causes organ dysfunction and failure

- Confirmatory Phase 3 AFFIRM-AL study results expected in 2024

ATTR Amyloidosis

PRX004, a potential first-in-class treatment for ATTR amyloidosis, is a humanized monoclonal antibody designed to deplete the pathogenic, non-native forms of the TTR protein, that is being developed by Novo Nordisk for the treatment of ATTR cardiomyopathy

- Novo Nordisk expects to initiate a Phase 2 study of PRX004 for the treatment of ATTR cardiomyopathy in 2Q 2022

Upcoming Investor Conferences

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

- BofA Securities 2022 Healthcare Conference, May 10, 2022, at 9:20 AM PT/12:20 PM ET
- H.C. Wainwright Global Investment Conference, May 24, 2022, on demand presentations available starting at 7:00 AM ET

First Quarter 2022 Financial Results

For the first quarter of 2022, Prothena reported a net loss of $36.3 million, as compared to a net loss of $36.7 million for the first quarter of 2021. Net loss per share for the first quarter of 2022 was $0.78, as compared to net loss per share of $0.91 for the first quarter of 2021.

Prothena reported total revenue of $1.2 million for the first quarter of 2022, primarily from collaboration revenue from Bristol Myers Squibb. As compared to total revenue of $0.2 million for the first quarter of 2021, from collaboration and license revenue from Roche.

Research and development (R&D) expenses totaled $27.3 million for the first quarter of 2022, as compared to $21.1 million for the first quarter of 2021. The increase in R&D expense for the first quarter of 2022 compared to the same period in the prior year was primarily due to higher manufacturing costs, primarily related to the birtamimab program, higher personnel related expenses, higher clinical trial expenses primarily related to the PRX012, birtamimab and PRX005 programs, and higher other R&D expense, offset in part by lower collaboration expenses related to the prasinezumab program with Roche as a result of the cost share opt-out exercised in May 2021. R&D expenses included non-cash share-based compensation expense of $3.3 million for the first quarter of 2022, as compared to $2.0 million for the first quarter of 2021.

General and administrative (G&A) expenses totaled $11.8 million for the first quarter of 2022, as compared to $11.1 million for the first quarter of 2021. The increase in G&A expenses for the first quarter of 2022 compared to the same period in the prior year was primarily related to higher personnel expense and higher consulting expenses, offset in part by lower legal expense and lower expense for our director and officer insurance premium. G&A expenses included non-cash share-based compensation expense of $4.3 million for the first quarter of 2022, as compared to $4.2 million for the first quarter of 2021.
Total non-cash share-based compensation expense was $7.7 million for the first quarter of 2022, as compared to $6.2 million for the first quarter of 2021.

As of March 31, 2022, Prothena had $544.3 million in cash, cash equivalents and restricted cash, and no debt.

As of April 28, 2022, Prothena had approximately 46.8 million ordinary shares outstanding.

2022 Financial Guidance

The Company continues to expect the full year 2022 net cash used in operating and investing activities to be $120 to $132 million, which includes an expected $40 million clinical milestone payment from Novo Nordisk and expects to end the year with approximately $454 million in cash, cash equivalents and restricted cash (midpoint). The estimated full year 2022 net cash used in operating and investing activities is primarily driven by an estimated net loss of $154 to $170 million, which includes an estimated $32 million of non-cash share-based compensation expense.

About Prothena

Prothena Corporation plc is a late-stage clinical biotechnology company with expertise in protein dysregulation and a pipeline of 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 pipeline includes both wholly-owned and partnered programs being developed for the potential treatment of diseases including AL amyloidosis, ATTR amyloidosis, Alzheimer's disease, Parkinson's disease and a number of other neurodegenerative diseases. 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 continued advancement of our discovery, preclinical, and clinical pipeline, and expected milestones in 2022 and beyond; our goal to continue building a biology-directed discovery engine targeting protein dysregulation and to change the Alzheimer's disease treatment paradigm; the treatment potential, designs, proposed mechanisms of action, and potential administration of birtamimab, prasinezumab, PRX004, PRX005, PRX012, and our dual Aβ/tau vaccine; plans for future clinical studies of birtamimab, prasinezumab, PRX004, PRX005, PRX012, and our dual Aβ/tau vaccine; and the expected timing of reporting data from clinical studies of birtamimab, prasinezumab, PRX005, and PRX012. 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 those described in the "Risk Factors" sections of our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 5, 2022, and discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the SEC. We undertake 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 our expectations.

PROTHENA CORPORATION PLC
CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited - amounts in thousands except per share data)

	Three Months Ended March 31,	
	2022	2021
Collaboration revenue	$ 1,103	$ 110
Revenue from license and intellectual property	50	50
Total revenue	1,153	160
Operating expenses:		
Research and development	27,262	21,144
General and administrative	11,835	11,125
Total operating expenses	39,097	32,269
Loss from operations	(37,944)	(32,109)
Other income (expense), net	(17)	34
Loss before income taxes	(37,961)	(32,075)
Provision for (benefit from) income taxes	(1,671)	4,660

Net loss	$ (36,290)	$ (36,735)
Basic and diluted net loss per ordinary share	$ (0.78)	$ (0.91)
Shares used to compute basic net loss per share	46,704	40,250

PROTHENA CORPORATION PLC

CONSOLIDATED BALANCE SHEETS

(unaudited - amounts in thousands)

	March 31, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 542,994	$ 579,094
Prepaid expenses and other current assets	12,626	5,715
Total current assets	555,620	584,809
Property and equipment, net	1,865	2,012
Operating lease right-of-use assets	10,664	12,123
Restricted cash, non-current	1,352	1,352
Other non-current assets	11,911	9,070
Total non-current assets	25,792	24,557
Total assets	$ 581,412	$ 609,366
Liabilities and Shareholders' Equity		
Accrued research and development	6,657	6,351
Deferred revenue, current	8,844	7,657
Lease liability, current	6,050	5,940
Other current liabilities	14,945	13,504
Total current liabilities	36,496	33,452
Deferred revenue, non-current	100,642	102,933
Lease liability, non-current	4,834	6,386
Other non-current liabilities	553	553
Total non-current liabilities	106,029	109,872
Total liabilities	142,525	143,324
Total shareholders' equity	438,887	466,042
Total liabilities and shareholders' equity	$ 581,412	$ 609,366

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