



NEWS RELEASE

Prothena Reports First Quarter 2023 Financial Results and Business Highlights

5/4/2023

- Net cash used in operating and investing activities was \$47.5 million in the first quarter of 2023; quarter-end cash and restricted cash position was \$688.4 million
- Data reported in an oral presentation at AD/PD 2023 that PRX012, a potential best-in-class anti-amyloid beta antibody, demonstrated higher affinity binding to amyloid beta soluble protofibrils and greater clearance of pyroglutamate-modified amyloid beta plaques compared to other approved and investigational molecules
- Topline data reported from Phase 1 SAD study of PRX005, a novel anti-MTBR-tau antibody, meeting the primary study objective

DUBLIN--(BUSINESS WIRE)-- 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 of 2023 and provided business highlights.

"Recent positive clinical study results and FDA approvals have now established that reduction of amyloid beta plaque is directly related to clinical benefit. These results are positive for the Alzheimer's disease community, especially for the patients, families and caregivers who fight everyday against this devastating disease. Prothena is committed to furthering these efforts by developing patient-centric, next-generation Alzheimer's disease treatments," said Gene Kinney, Ph.D., President and Chief Executive Officer, Prothena. "We showcased our potential best-in-class Alzheimer's disease portfolio in the first quarter of 2023 with new preclinical data presented at AD/PD which adds to the scientific foundation for our PRX012 program. These data demonstrated higher affinity binding to amyloid beta soluble protofibrils and greater clearance of pyroglutamate-modified amyloid beta plaques compared to other approved and investigational molecules. In addition, we released topline data from the Phase 1 SAD study of PRX005 which demonstrated that single doses of PRX005 across three dose cohorts were generally safe and well

tolerated.

“We look forward to making meaningful advances in our Alzheimer’s disease portfolio this year. We also continue to focus on enrolling our confirmatory Phase 3 AFFIRM-AL study of birtamimab, the first potential therapy to observe a significant survival benefit in patients with Mayo Stage IV AL amyloidosis,” added Kinney.

First Quarter, Recent Business Highlights and Upcoming Milestones

Neurodegenerative Diseases Portfolio

Alzheimer’s Disease (AD)

PRX012, a wholly-owned potential best-in-class, next-generation subcutaneous antibody for the treatment of AD, targets a key epitope at the N-terminus of amyloid beta (A β) with high binding potency. The U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for PRX012 for the treatment of AD.

- Multiple presentations at International Conference on Alzheimer’s and Parkinson’s Diseases 2023 (AD/PD) highlighted by an **oral presentation** of preclinical data showing superior binding characteristics of PRX012, demonstrated 20-fold higher affinity to A β soluble protofibrils when compared to lecanemab; PRX012 also cleared pyroglutamate-modified A β at lower concentrations when compared to donanemab
- Partnered with Walgreens to accelerate patient identification and recruitment for ongoing ASCENT-2 multiple ascending dose (MAD) clinical trial evaluating safety and tolerability
- Ongoing Phase 1 single ascending dose (SAD) and MAD studies; topline data expected year end 2023

PRX005, a potential best-in-class antibody for the treatment of AD, 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 a global neuroscience research and development collaboration with Bristol Myers Squibb.

- **Topline data** from Phase 1 SAD study announced January 2023 showing single doses of PRX005 across three dose cohorts were generally safe and well tolerated, meeting the primary study objective; results expected from the Phase 1 SAD study at an upcoming medical conference
- Ongoing Phase 1 MAD study; topline data expected by year end 2023

PRX123, a wholly-owned potential first-in-class dual A β /tau vaccine for the treatment and prevention of AD, is a dual-target vaccine targeting key epitopes within the N-terminus of A β and MTBR-tau designed to promote amyloid clearance and block the transmission of pathogenic tau

- Investigational new drug (IND) application filing expected by year end 2023

Parkinson's Disease (PD)

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

- Poster and oral presentations at AD/PD highlighted aspects of the Phase 2 PASADENA study of prasinezumab for the treatment of PD
- In Q1 2023, Roche completed enrollment for the Phase 2b PADOVA trial in patients with early PD (NCT04777331); topline data expected in 2024

Rare Peripheral Amyloid Diseases Portfolio

AL Amyloidosis

Birtamimab, a wholly-owned potential best-in-class amyloid depleter antibody for the treatment of AL amyloidosis, is designed to directly neutralize soluble toxic aggregates and promote clearance of amyloid that causes organ dysfunction and failure. Among patients with AL amyloidosis, a rare, progressive, and fatal disease, newly diagnosed individuals with advanced disease (i.e. Mayo Stage IV) are at the highest risk for early death. Birtamimab has been granted Fast Track Designation by the FDA for the treatment of patients with Mayo Stage IV AL amyloidosis to reduce the risk of mortality and has been granted Orphan Drug Designation by both the FDA and European Medicines Agency.

- Confirmatory Phase 3 AFFIRM-AL trial in patients with Mayo Stage IV AL amyloidosis, which is under a Special Protocol Assessment (SPA) with the FDA with a primary endpoint of all-cause mortality at $p \leq 0.10$, is ongoing (NCT04973137); topline data expected in 2024

ATTR Amyloidosis

NNC6019 (formerly PRX004), a potential first-in-class amyloid depleter antibody for the treatment of ATTR cardiomyopathy, is designed to deplete the pathogenic, non-native forms of the transthyretin (TTR) protein and is being developed by Novo Nordisk as part of their up to \$1.2 billion acquisition of Prothena's ATTR amyloidosis business and pipeline

- Ongoing Phase 2 study in patients with ATTR cardiomyopathy is being conducted by Novo Nordisk (NCT05442047); topline data expected in 2024

First Quarter of 2023 Financial Results

For the first quarter of 2023, Prothena reported net loss of \$46.9 million, as compared to a net loss of \$36.3 million for the first quarter of 2022. Net loss per share was \$0.89 for the first quarter of 2023, as compared to net loss per share of \$0.78 for the first quarter of 2022.

Prothena reported total revenue of \$2.2 million for the first quarter of 2023, as compared to total revenue of \$1.2 million for the first quarter of 2022, primarily from collaboration revenue from Bristol Myers Squibb.

Research and development (R&D) expenses totaled \$44.8 million for the first quarter of 2023, as compared to \$27.3 million for the first quarter of 2022. The increase in R&D expense for the first quarter of 2023 compared to the same period in the prior year was primarily due to higher clinical trial expenses, higher personnel related expenses, higher consulting and other R&D expenses. R&D expenses included non-cash share-based compensation expense of \$4.4 million for the first quarter of 2023, as compared to \$3.3 million for the first quarter of 2022.

General and administrative (G&A) expenses totaled \$13.7 million for the first quarter of 2023, as compared to \$11.8 million for the first quarter of 2022. The increase in G&A expenses for the first quarter of 2023 compared to the same period in the prior year was primarily related to higher personnel related and legal expenses. G&A expenses included non-cash share-based compensation expense of \$4.4 million for the first quarter of 2023, as compared to \$4.3 million for the first quarter of 2022.

Total non-cash share-based compensation expense was \$8.8 million for the first quarter of 2023, as compared to \$7.7 million for the first quarter of 2022.

As of March 31, 2023, Prothena had \$688.4 million in cash, cash equivalents and restricted cash, and no debt.

As of April 28, 2023, Prothena had approximately 52.8 million ordinary shares outstanding.

2023 Financial Guidance

The Company continues to expect the full year 2023 net cash used in operating and investing activities to be \$213 to \$229 million and expects to end the year with approximately \$512 million in cash, cash equivalents and restricted cash (midpoint). The estimated full year 2023 net cash used in operating and investing activities is primarily driven by an estimated net loss of \$250 to \$275 million, which includes an estimated \$46 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 2023 and beyond; the treatment potential, designs, proposed mechanisms of action, and potential administration of birtamimab, prasinezumab, NNC6019/PRX004, PRX005, PRX012, and PRX123; plans for future clinical studies of birtamimab, prasinezumab, NNC6019/PRX004, PRX005, PRX012, and PRX123 (including the filing of an IND application); the expected timing of reporting data from clinical studies of birtamimab, prasinezumab, PRX005, and PRX012; our anticipated net cash burn from operating and investing activities for 2023 and expected cash balance at the end of 2023; and our estimated net loss and non-cash share-based compensation expense for 2023. 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 4, 2023, 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 CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (unaudited - amounts in thousands except per share data)

	Three Months Ended March 31,	
	2023	2022
Collaboration revenue	\$ 2,119	\$ 1,103
Revenue from license and intellectual property	50	50
Total revenue	2,169	1,153
Operating expenses:		
Research and development	44,756	27,262

General and administrative	13,738	11,835
Total operating expenses	58,494	39,097
Loss from operations	(56,325)	(37,944)
Other income (expense), net	6,549	(17)
Loss before income taxes	(49,776)	(37,961)
Benefit from income taxes	(2,912)	(1,671)
Net loss	<u>\$ (46,864)</u>	<u>\$ (36,290)</u>
Basic net loss per ordinary share	\$ (0.89)	\$ (0.78)
Diluted net loss per ordinary share	\$ (0.89)	\$ (0.78)
Shares used to compute basic net loss per share	52,501	46,704
Shares used to compute diluted net loss per share	52,501	46,704

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

	March 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	\$ 686,184	\$ 710,406
Prepaid expenses and other current assets	14,159	8,692
Total current assets	700,343	719,098
Property and equipment, net	1,924	1,731
Operating lease right-of-use assets	4,719	6,277
Restricted cash, non-current	2,212	2,212
Other non-current assets	32,388	28,717
Total non-current assets	41,243	38,937
Total assets	<u>\$ 741,586</u>	<u>\$ 758,035</u>
Liabilities and Shareholders' Equity		
Accrued research and development	14,156	10,794
Deferred revenue, current	9,323	11,442
Lease liability, current	4,885	6,473
Other current liabilities	20,520	21,438
Total current liabilities	48,884	50,147
Deferred revenue, non current	85,293	85,293
Other non-current liabilities	—	553
Total non-current liabilities	85,293	85,846
Total liabilities	134,177	135,993
Total shareholders' equity	607,409	622,042
Total liabilities and shareholders' equity	<u>\$ 741,586</u>	<u>\$ 758,035</u>

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