



NEWS RELEASE

Prothena Reports Third Quarter 2022 Financial Results and Business Highlights

11/3/2022

- Net cash used in operating and investing activities was \$31.3 million in the third quarter and \$104.2 million for the first nine months of 2022; quarter-end cash and restricted cash position was \$497.0 million
- Phase 3 VITAL study data on observed survival benefit in Mayo Stage IV AL amyloidosis patients treated with birtamimab selected for oral presentation at ASH 2022 meeting

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 third quarter and first nine months of 2022 and provided a business update.

“Significant scientific and clinical progress has reinforced our understanding of the biology of Alzheimer’s disease and the impact that lowering amyloid plaque has on slowing cognitive and functional decline of people suffering from this devastating condition. This further strengthens our belief that PRX012, our next-generation subcutaneous anti-A β antibody, with a best-in-class profile, is positioned to lead a paradigm shift in the treatment of Alzheimer’s disease. Additionally, we look forward to presenting data on the observed survival benefit of birtamimab from the Phase 3 VITAL study in patients with Mayo Stage IV AL amyloidosis during an oral presentation at ASH next month,” said Gene Kinney, Ph.D., President and Chief Executive Officer of Prothena. “With our deep portfolio of investigational therapies and a strong cash position, Prothena remains well positioned to address the urgent needs of patients affected by neurodegenerative and rare peripheral amyloid diseases.”

[Third Quarter and Recent Business Highlights and Upcoming Milestones](#)

[Neurodegenerative Diseases Portfolio](#)



Alzheimer's Disease (AD)

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

- Phase 1 multiple ascending dose (MAD) study initiation expected by year-end 2022
- Topline data from Phase 1 study 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 data from Phase 1 study expected by year-end 2022

PRX123, a potential first-in-class dual A β /tau vaccine treatment and prevention therapy for AD, is a dual-target vaccine targeting key epitopes within the A β and tau proteins to promote amyloid clearance and blockade of pathogenic 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

- Phase 2b PADOVA study in patients with early PD is being conducted by Roche (NCT04777331); topline data 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

- Poster presented at the XVIII International Symposium on Amyloidosis (ISA) on September 5, 2022 titled: Birtamimab in Patients with Mayo Stage IV AL Amyloidosis: Rationale for Confirmatory AFFIRM-AL Phase 3 Study
- Abstract selected for oral presentation on Monday December 12, 2022, at 11:15 AM ET at the 2022 American Society of Hematology (ASH) Annual Meeting and Exposition titled: Survival Benefit of Birtamimab in Mayo Stage IV AL Amyloidosis in the Phase 3 VITAL Study Consistent After Adjustment for Baseline Variables
- Confirmatory Phase 3 AFFIRM-AL topline data expected in 2024

ATTR Amyloidosis

NNC6019 (formerly 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 transthyretin (TTR) protein, that is being developed by Novo Nordisk for the treatment of ATTR cardiomyopathy

- Phase 2 trial of NNC6019 in patients with ATTR cardiomyopathy is being conducted by Novo Nordisk (NCT05442047)

Upcoming Investor Conferences

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

- Jefferies 2022 London Healthcare Conference on Wednesday, November 16, 2022, a fireside chat will be held at 12:00 PM ET
- Jefferies 5th Annual Denver Biopharma Summit on Wednesday, December 14, 2022, 1x1 investor meetings will be held

Third Quarter and First Nine Months of 2022 Financial Results

For the third quarter and first nine months of 2022, Prothena reported a net loss of \$45.8 million and \$123.3 million, respectively, as compared to a net income of \$109.2 million and \$100.2 million for the third quarter and first nine months of 2021, respectively. Net loss per share for the third quarter of 2022 and first nine months of 2022 was \$0.97, and \$2.63, respectively, as compared to net income per share on a diluted basis of \$2.13 and \$2.12 for the third quarter and first nine months of 2021, respectively.

Prothena reported total revenue of \$1.5 million and \$4.0 million for the third quarter and first nine months of 2022, respectively, primarily from collaboration revenue from BMS. As compared to total revenue of \$139.2 million and \$199.4 million for the third quarter and first nine months of 2021, respectively. Revenue for the third quarter of

2021 included collaboration revenue of \$78.5 million from BMS for the option exercise and US license for PRX005 and \$60.7 million from the sale of the clinical stage antibody NNC6019 (formerly PRX004) program and related rights to the Company's ATTR amyloidosis business and pipeline to Novo Nordisk. In addition to third quarter 2021 revenue, the first nine months of 2021 revenue included collaboration revenue of \$60 million in clinical milestone payment from Roche for dosing of first patient in the global Phase 2b PADOVA study for prasinezumab and license revenue from Roche.

Research and development (R&D) expenses totaled \$39.9 million and \$98.7 million for the third quarter and first nine months of 2022, respectively, as compared to \$18.0 million and \$60.2 million for the third quarter and first nine months of 2021, respectively. The increase in R&D expense for the third quarter and first nine months of 2022 compared to the same periods in the prior year was primarily due to higher manufacturing costs primarily related to the birtamimab, PRX012, PRX019, PRX123 and PRX005 programs, higher personnel related expenses, higher clinical trial expenses primarily related to the PRX012 and birtamimab programs, higher other R&D expense and higher consulting expenses. For the nine months ended September 30, 2022, the higher costs were 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 and lower manufacturing expenses related to the NNC6019 (formerly PRX004) program. R&D expenses included non-cash share-based compensation expense of \$4.2 million and \$11.3 million for the third quarter and first nine months of 2022, respectively, as compared to \$2.5 million and \$6.6 million for the third quarter and first nine months of 2021, respectively.

General and administrative (G&A) expenses totaled \$12.0 million and \$36.8 million for the third quarter and first nine months of 2022, respectively, as compared to \$12.0 million and \$34.1 million for the third quarter and first nine months of 2021, respectively. The increase in G&A expenses for the third quarter and first nine months of 2022 compared to the same periods in the prior year was primarily related to higher personnel related expenses, offset in part by lower legal expenses. G&A expenses included non-cash share-based compensation expense of \$3.8 million and \$12.6 million for the third quarter and first nine months of 2022, respectively, as compared to \$3.6 million and \$11.1 million for the third quarter and first nine months of 2021, respectively.

Total non-cash share-based compensation expense was \$8.0 million and \$23.9 million for the third quarter and first nine months of 2022, respectively, as compared to \$6.1 million and \$17.8 million for the third quarter and first nine months of 2021, respectively.

As of September 30, 2022, Prothena had \$497.0 million in cash, cash equivalents and restricted cash, and no debt.

As of October 26, 2022, Prothena had approximately 48.4 million ordinary shares outstanding.

2022 Financial Guidance

The Company is updating its projected full year 2022 net cash burn from operating and investing activities, and expects it to be \$108 to \$120 million (versus prior guidance of \$120 to \$132 million) which includes an expected \$40 million clinical milestone payment from Novo Nordisk, and expects to end the year with approximately \$522 million in cash, cash equivalents, and restricted cash (midpoint) (versus prior guidance of \$454 million) which is primarily driven by operating and financing activities. The updated estimated full year 2022 net cash burn from operating and investing activities is primarily driven by an updated estimated net loss of \$121 to \$137 million (versus prior guidance of \$154 to \$170 million), which includes an estimated \$31 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, 2023, and beyond; the treatment potential, designs, proposed mechanisms of action, and potential administration of birtamimab, prasinezumab, NNC6019 (formerly PRX004), PRX005, PRX012, and PRX123; plans for future clinical studies of birtamimab, prasinezumab, NNC6019 (formerly PRX004), PRX005, PRX012, and PRX123; 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 November 3, 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration revenue	\$ 1,517	\$ 78,480	\$ 3,932	\$ 138,661
Revenue from license and intellectual property	—	60,694	50	60,744
Total revenue	1,517	139,174	3,982	199,405
Operating expenses:				
Research and development	39,860	17,992	98,691	60,226
General and administrative	11,989	11,955	36,776	34,112
Total operating expenses	51,849	29,947	135,467	94,338
Income (loss) from operations	(50,332)	109,227	(131,485)	105,067
Other income (expense), net	1,915	(31)	2,535	(50)
Income (loss) before income taxes	(48,417)	109,196	(128,950)	105,017
Provision for (benefit from) income taxes	(2,653)	(51)	(5,652)	4,863
Net income (loss)	\$ (45,764)	\$ 109,247	\$ (123,298)	\$ 100,154
Basic net income (loss) per ordinary share	\$ (0.97)	\$ 2.39	\$ (2.63)	\$ 2.31
Diluted net income (loss) per ordinary share	\$ (0.97)	\$ 2.13	\$ (2.63)	\$ 2.12
Shares used to compute basic net income (loss) per share	46,986	45,626	46,833	43,422
Shares used to compute diluted net income (loss) per share	46,986	51,205	46,833	47,196

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

	September 30, 2022	December 31, 2021
Assets		
Cash and cash equivalents	\$ 495,628	\$ 579,094
Prepaid expenses and other current assets	28,934	5,715
Total current assets	524,562	584,809
Property and equipment, net	1,997	2,012
Operating lease right-of-use assets	7,808	12,123
Restricted cash, non-current	1,352	1,352
Other non-current assets	18,721	9,070
Total non-current assets	29,878	24,557
Total assets	\$ 554,440	\$ 609,366
Liabilities and Shareholders' Equity		
Accrued research and development	11,593	6,351
Deferred revenue, current	9,665	7,657
Lease liability, current	6,385	5,940
Other current liabilities	22,955	13,504
Total current liabilities	50,598	33,452
Deferred revenue, non current	96,992	102,933
Lease liability, non-current	1,649	6,386
Other non-current liabilities	553	553
Total non-current liabilities	99,194	109,872
Total liabilities	149,792	143,324
Total shareholders' equity	404,648	466,042
Total liabilities and shareholders' equity	\$ 554,440	\$ 609,366

Investors

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Source: Prothena Corporation plc