Prothena Reports Second Quarter 2021 Financial Results and Business Highlights

August 5, 2021

- **Net cash provided by operating and investing activities was $36.6 million in the second quarter and $2.9 million for the first six months of 2021; quarter-end cash and restricted cash position of $402.5 million (includes $60 million payment from Roche) provides additional funding to continue advancing R&D pipeline**
- **Announced multiple strategic collaborations delivering milestones in 2021 and potentially beyond**
- **Presented preclinical data at AAIC for two product candidates being developed for Alzheimer's disease, PRX012 next-generation anti-Aβ antibody and dual Aβ-tau vaccine**

DUBLIN, Ireland, Aug. 05, 2021 (GLOBE NEWSWIRE) -- Prothena Corporation plc (NASDAQ:PRTA), a late-stage clinical company with a robust pipeline of novel investigational therapeutics built on protein dysregulation expertise, today reported financial results for the second quarter and first six months of 2021. In addition, the Company provided business highlights and updated 2021 financial guidance.

"We continued to make significant progress advancing our robust portfolio with our confirmatory Phase 3 AFFIRM-AL trial of birtamimab in AL amyloidosis and new preclinical data presented at AAIC that highlighted two of our potentially best-in-class Alzheimer's programs, PRX012, a high-potency anti-Aβ antibody designed for subcutaneous administration to enhance patient access and compliance, and our dual Aβ-tau vaccine for the prevention and treatment of Alzheimer's," said Gene Kinney, Ph.D., President and Chief Executive Officer of Prothena. "Additionally, multiple strategic collaborations delivered milestones with a combined $200 million in partner payments this year from Roche, Bristol Myers Squibb and Novo Nordisk. Progress across our portfolio continues to validate our scientific platform and capital earned through our strategic partnerships helps to advance our robust pipeline through key milestones. As we continue to work towards our mission to bring novel therapies to patients in need of new treatment options, we welcomed Sanjiv Patel to our board, who brings significant industry experience to advise Prothena as we transition to a fully integrated research, development and commercial biotechnology company."

Second Quarter and Recent Business Highlights:

Multiple milestones from strategic collaborations

- $60 million milestone from Roche for prasinezumab received in 2Q 2021
- $80 million milestone from Bristol Myers Squibb for PRX005 expected in 3Q 2021
- Up to $1.23 billion from Novo Nordisk for ATTR amyloidosis, including $60 million upfront payment received in 3Q 2021 and $40 million milestone expected 1H 2022

Birtamimab, a potential treatment for AL amyloidosis, is a 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 of birtamimab in Mayo Stage IV patients with AL amyloidosis (NCT#04973137)

Prasinezumab, a potential treatment for Parkinson's disease, is a humanized monoclonal antibody designed to target a key epitope within the C-terminus of alpha-synuclein and is the focus of the worldwide collaboration with Roche

- Earned $60 million clinical milestone payment upon dosing of the first patient in the global Phase 2b PADOVA study for prasinezumab, which was announced in May 2021 (NCT#04777331)

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

- Announced Novo Nordisk acquisition of ATTR amyloidosis business; Prothena is eligible to receive development and sales milestones up to $1.23 billion
    - Includes $100 million in upfront and near-term milestone payments (received $60 million upfront in 3Q 2021 and potential for $40 million upon initiation of Phase 2 study in ATTR cardiomyopathy patients)

PRX005, a potential treatment for Alzheimer's disease (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

- Bristol Myers Squibb exercised its option under the global neuroscience research and development collaboration and entered into an exclusive U.S. license for PRX005. Prothena is expected to receive $80 million from Bristol Myers Squibb

in 3Q 2021.

- Phase 1 study initiated

PRX012, a potential best-in-class treatment for AD, is a high-potency monoclonal antibody targeting a key epitope at the N-terminus of Aβ

- Results presented at the Alzheimer's Association International Conference® 2021 (AAIC®) demonstrated that PRX012 induced significant microglia-mediated clearance of both pyroglutamate-modified and -unmodified Aß plaque in brain tissue of late-stage AD patients at concentrations predicted to be clinically relevant. Both forms have been described as components of senile plaque and vascular Aβ in AD. PRX012 was observed to bind with very high affinity/avidity to full-length Aβ. PRX012 also showed higher potency and greater biologic activity than aducanumab in preclinical studies.

Dual Aβ-Tau vaccine, a potential prevention and treatment for Alzheimer's disease, is a dual vaccine targeting key epitopes within the Aβ and tau proteins to promote amyloid clearance and blockade pathogenic tau interaction

- Results presented at AAIC demonstrated Prothena's dual Aβ-tau vaccine constructs generated appropriate antibody quantities with the ability to promote both phagocytosis of Aβ plaque and blockade of tau binding to a heparin-sulfate analog, which is a surrogate for neuronal uptake of tau. All three constructs generated a balanced immune response to both proteins, a common challenge with multi-epitope vaccines, and induced robust antibody titers to Aβ and tau in multiple animal experiments. The resultant titers strongly reacted with Aβ and tau pathology in human AD brain tissue. Additionally, cerebrospinal fluid (CSF) concentrations of tau and Aβ antibodies were within the expected range and similar to typical ranges achieved following administration of monoclonal antibodies (0.1-0.2% CSF/plasma).

Corporate

- Appointed Sanjiv K. Patel, MBBS, MA, MBA, to its Board of Directors. Dr. Patel is President, Chief Executive Officer, and a member of the board of Relay Therapeutics, a clinical stage precision medicine company. Before joining Relay Therapeutics, Dr. Patel served in various roles at Allergan, Inc. for over a decade. He most recently served as Allergan's Executive Vice President, Chief Strategy Officer and previously as Corporate Vice President, Global Strategic Marketing and Global Health Outcomes. Prior to this, he was a management consultant at The Boston Consulting Group and practiced as a surgeon within the UK's National Health Service.

Upcoming Milestones:

Birtamimab

- VITAL study 9-month results expected to be presented at a medical conference in 2021

Prasinezumab

- Results from Part 2 of the PASADENA study expected to be presented at an upcoming medical conference

PRX004

- $40 million milestone payment from Novo Nordisk for Phase 2 initiation expected 1H 2022

PRX005

- $80 million option payment from Bristol Myers Squibb expected in 3Q 2021
- Potential $55 million option payment from Bristol Myers Squibb for global rights at the end of Phase 1

PRX012

- Investigational New Drug Application (IND) expected 1Q 2022

Dual Aβ-Tau vaccine

- IND expected 2023

Second Quarter and First Six Months of 2021 Financial Results and Updated 2021 Financial Guidance

For the second quarter and first six months of 2021, Prothena reported a net income of $27.6 million and a net loss of $9.1 million, respectively, as compared to a net loss of $26.3 million and $49.9 million for the second quarter and first six months of 2020, respectively. Net income per share on a diluted basis for the second quarter of 2021 was $0.58 and net loss per share for the first six months of 2021, was $0.21, as compared to net loss per share of $0.66 and $1.25 for the second quarter and first six months of 2020, respectively.

Prothena reported total revenue of $60.1 million and $60.2 million for the second quarter and first six months of 2021, respectively, from collaboration and license revenue from Roche, as compared to total revenue of $0.2 million and $0.3 million for the second quarter and first six months of 2020,

from collaboration and license revenue from Roche.

Research and development (R&D) expenses totaled $21.1 million and $42.2 million for the second quarter and first six months of 2021, respectively, as compared to $17.3 million and $32.5 million for the second quarter and first six months of 2020, respectively. The increase in R&D expense for the second quarter and first six months of 2021, compared to the same period in the prior year was primarily due to higher personnel expense, higher consulting expense, higher manufacturing expense primarily related to our PRX004 and PRX012 programs, higher clinical trial expense primarily related to birtamimab AFFIRM-AL trial, partially offset by lower PRX004 clinical trial expenses and lower collaboration expense with Roche related to the prasinezumab program as a result of the May 2021, cost share opt-out. R&D expenses included non-cash share-based compensation expense of $2.2 million and $4.2 million for the second quarter and first six months of 2021, respectively, as compared to $2.1 million and $4.1 million for the second quarter and first six months of 2020, respectively.

General and administrative (G&A) expenses totaled $11.0 million and $22.2 million for the second quarter and first six months of 2021, respectively, as compared to $9.7 million and $19.4 million for the second quarter and first six months of 2020, respectively. The increase in G&A expenses for the second quarter and first six months of 2021 compared to the same period in the prior year was primarily related to higher personnel expense, higher legal expense and higher expense for our director and officer insurance premium. G&A expenses included non-cash share-based compensation expense of $3.3 million and $7.5 million for the second quarter and first six months of 2021, respectively, as compared to $3.6 million and $7.1 million for the second quarter and first six months of 2020, respectively.

Total non-cash share-based compensation expense was $5.5 million and $11.7 million for the second quarter and first six months of 2021, respectively, as compared to $5.7 million and $11.2 million for the second quarter and first six months of 2020.

As of June 30, 2021, Prothena had $402.5 million in cash, cash equivalents and restricted cash (does not include the $60 million upfront payment from Novo Nordisk received in 3Q 2021 or the $80 million from Bristol Myers Squibb for the exclusive U.S. license to PRX005 expected in 3Q 2021) and no debt.

As of July 29, 2021, Prothena had approximately 45.0 million ordinary shares outstanding.

The Company is updating its projected full year 2021 net cash burn from operating and investing activities (prior guidance of $51 to $74 million) to net cash provided by operating and investing activities of $85 to $95 million and expects to end the year with approximately $491 million in cash, cash equivalents and restricted cash (midpoint) representing an increase of $175 million from prior guidance of $316 million. This increase in cash position is primarily driven by an $80 million milestone payment from Bristol Myers Squibb expected in 3Q 2021 for the exclusive U.S. license to PRX005 and a $60 million payment received from Novo Nordisk in 3Q 2021 for the acquisition of Prothena's ATTR amyloidosis business, which are both included in operating activities. The updated estimated full year 2021 net cash provided by operating and investing activities is primarily driven by an updated estimated net income of $50 to $60 million (versus prior net loss guidance of $79 to $111 million), which includes the payments from Bristol Myers Squibb and Novo Nordisk mentioned above, as well as an estimated $25 million of non-cash share-based compensation expense.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Collaboration revenue	$ 60,071	$ 145	$ 60,181	$ 286
License revenue	—	50	50	50
Total revenue	60,071	195	60,231	336
Operating expenses:				
Research and development	21,090	17,271	42,234	32,519
General and administrative	11,032	9,656	22,157	19,397
Total operating expenses	32,122	26,927	64,391	51,916
Income (loss) from operations	27,949	(26,732)	(4,160)	(51,580)
Other income (expense), net	(53)	195	(19)	1,308
Income (loss) before income taxes	27,896	(26,537)	(4,179)	(50,272)
Provision for (benefit from) income taxes	254	(255)	4,914	(421)
Net income (loss)	$ 27,642	$ (26,282)	$ (9,093)	$ (49,851)
Basic net income (loss) per ordinary share	$ 0.62	$ (0.66)	$ (0.21)	$ (1.25)
Diluted net income (loss) per ordinary share	$ 0.58	$ (0.66)	$ (0.21)	$ (1.25)
Shares used to compute basic net income (loss) per share	44,332	39,911	42,302	39,910
Shares used to compute diluted net income (loss) per share	47,414	39,911	42,302	39,910

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

	June 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 399,831	$ 295,380
Accounts receivable	3	15
Prepaid expenses and other current assets	8,282	2,537

Restricted cash, current	1,352	1,352
Total current assets	409,468	299,284
Property and equipment, net	2,080	2,551
Operating lease right-of-use assets	14,996	17,811
Restricted cash, non-current	1,352	1,352
Other non-current assets	8,482	11,977
Total non-current assets	26,910	33,691
Total assets	$ 436,378	$ 332,975
Liabilities and Shareholders' Equity		
Accrued research and development	8,375	9,044
Deferred revenue, current	24,949	—
Lease liability, current	5,723	5,512
Other current liabilities	13,852	11,292
Total current liabilities	52,899	25,848
Deferred revenue, non current	85,293	110,242
Lease liability, non-current	9,426	12,326
Other non-current liabilities	553	553
Total non-current liabilities	95,272	123,121
Total liabilities	148,171	148,969
Total shareholders' equity	288,207	184,006
Total liabilities and shareholders' equity	$ 436,378	$ 332,975

About Prothena

Prothena Corporation plc is a late-stage clinical company with a robust pipeline of novel investigational therapeutics built on protein dysregulation expertise with the potential to change the course of devastating rare peripheral amyloid and neurodegenerative 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; our goal of building a protein dysregulation platform; the treatment potential, designs, and proposed mechanisms of action 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; amounts we might receive under our strategic collaborations with Roche, Bristol Myers Squibb and Novo Norkdisk; the expected timing of reporting data from prior clinical studies of birtamimab and the Phase 2 clinical study of prasinezumab; our anticipated net cash burn from operating and investing activities for 2021 and expected cash balance at the end of 2021; and our estimated net loss and non-cash share-based compensation expense for 2021. 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 August 5, 2021, as well as 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.

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