



May 3, 2016

## Prothena Reports First Quarter 2016 Financial Results and Provides R&D Update

- | **Net cash used in operating and investing activities was \$25.4 million in the first quarter; strong quarter-end cash position of \$474.3 million, including net proceeds of \$128.6 million raised through January 2016 public equity offering, supports advancement of multiple clinical development programs**
- | **Initiated PRONTO, a registration-directed, global Phase 2b trial of NEOD001 in patients with AL amyloidosis**
- | **Initiated Phase 1b multiple ascending dose, proof-of-biology study of PRX003 in patients with psoriasis**
- | **Appointed experienced biotechnology executive David B. McNinch as Chief Commercial Officer**

DUBLIN, Ireland, May 03, 2016 (GLOBE NEWSWIRE) -- Prothena Corporation plc (NASDAQ:PRTA), a late-stage clinical biotechnology company focused on the discovery, development and commercialization of novel protein immunotherapies, today reported financial results for the first quarter ended March 31, 2016. In addition, the Company provided an update on its R&D programs.

"During the first quarter of 2016, we initiated clinical trials for NEOD001 and PRX003," said Dale Schenk, PhD, President and Chief Executive Officer of Prothena. "Enrollment is now progressing for both the Phase 2b PRONTO trial in patients with AL amyloidosis which advances our comprehensive pivotal program for NEOD001, and the Phase 1b multiple ascending dose trial in patients with psoriasis which investigates PRX003 as a new approach to addressing immune-mediated diseases. As we look toward planning for commercialization of NEOD001, we also welcomed the addition of David McNinch as Chief Commercial Officer. Looking ahead, we expect to report new data for all three of our clinical programs this year, and continue to advance our overall business with support of our balance sheet."

### Recent Highlights and Program Updates:

- | Initiated PRONTO, a randomized, registration-directed, global Phase 2b trial of NEOD001 in previously-treated patients with AL amyloidosis and persistent cardiac dysfunction. The primary endpoint of the trial is best response over 12 months of a cardiac functional biomarker, defined by the consensus criteria of NT-proBNP change.
- | Initiated a double-blind, placebo-controlled Phase 1b multiple ascending dose study of PRX003 in patients with psoriasis. Because of the visual, defined nature of psoriasis, Prothena expects to be able to rapidly assess the biological activity of PRX003 and establish a clinical foundation to inform the strategic development pathway for psoriasis and other indications in inflammatory disease.
- | Published interim results from the Phase 1/2 clinical trial of NEOD001 in patients with AL amyloidosis and persistent organ dysfunction in the peer-reviewed Journal of Clinical Oncology. The paper is entitled, "[First-in-Human Phase 1/2 Study of NEOD001 in Patients with Light Chain Amyloidosis and Persistent Organ Dysfunction](#)".
- | Published preclinical data from a series of novel, conformation-specific protein immunotherapy antibodies that selectively bind to amyloidogenic (diseased) forms of the transthyretin (ATTR) protein in the peer-reviewed journal Amyloid. In the rare disease known as transthyretin-mediated amyloidosis (ATTR amyloidosis), aggregation of a mutant, misfolded form of the transthyretin protein can impact organs such as the heart or nervous system. The paper is entitled "[Novel conformation-specific monoclonal antibodies against amyloidogenic forms of transthyretin](#)".
- | [Presented preclinical data](#) for PRX003 at the American Academy of Allergy, Asthma & Immunology (AAAAI) 2016 Annual Meeting demonstrating the ability of PRX003 to inhibit migration of disease-causing immune cells.
- | [Appointed David B. McNinch as Chief Commercial Officer](#), a new executive role to shape and implement an integrated global commercial strategy in preparation for the potential introduction of our lead clinical compound NEOD001.
- | Completed a successful public offering that raised aggregate net proceeds of \$128.6 million through the issuance of approximately 2.6 million ordinary shares.

### Upcoming Research and Development Milestones

Prothena's clinical development pipeline includes three lead protein immunotherapy programs.

**NEOD001** is a monoclonal antibody that targets circulating misfolded soluble light chain and deposited insoluble amyloid for the potential treatment of AL amyloidosis:

- | Expect to present topline results from the expansion cohort of the Phase 1/2 study in the second quarter of 2016.
- | Expect to complete enrollment in the Phase 3 VITAL Amyloidosis Study in the second quarter of 2017.
- | Expect topline results from the Phase 2b PRONTO trial in late 2017 - early 2018.

**PRX002** is a monoclonal antibody that targets  $\alpha$ -synuclein, for the potential treatment of Parkinson's disease and related synucleinopathies, and is the primary focus of Prothena's worldwide collaboration with Roche:

- | Expect topline results from Phase 1 multiple ascending dose study in patients with Parkinson's disease in the fourth quarter of 2016.

**PRX003** is a monoclonal antibody that targets melanoma cell adhesion molecule (MCAM), believed to be a critical mediator of Th17 cell pathogenesis, for the potential treatment of inflammatory diseases, including psoriasis:

- | Expect topline results from Phase 1 single ascending dose study in healthy volunteers in the second quarter of 2016.
- | Expect topline results from Phase 1b multiple ascending dose, proof-of-biology study in patients with psoriasis in the second half of 2017.

### **First Quarter 2016 Financial Results and Guidance**

Prothena reported a net loss of \$27.5 million for the first quarter of 2016, as compared to a net loss of \$15.2 million for the first quarter of 2015. Net loss per share for the first quarter of 2016 was \$0.81, as compared to a net loss per share for the first quarter of 2015 of \$0.55.

Prothena reported total revenue of \$0.3 million for the first quarter of 2016, as compared to total revenue of \$0.6 million for the first quarter of 2015. The decrease in revenue for the first quarter of 2016 was primarily due to lower revenue from Prothena's collaboration agreement with Roche.

Research and development (R&D) expenses totaled \$20.5 million for the first quarter of 2016, as compared to \$10.6 million for the first quarter of 2015. The increase in R&D expenses for the first quarter of 2016 was primarily due to increased expenses related to clinical trials, manufacturing, and personnel costs. R&D expenses included non-cash share-based compensation expense of \$1.4 million for the first quarter of 2016, as compared to \$0.8 million first quarter of 2015.

General and administrative (G&A) expenses totaled \$7.2 million for the first quarter of 2016, as compared to \$5.0 million for first quarter of 2015. The increase in G&A expenses for the first quarter of 2016 was primarily due to increases in personnel costs. G&A expenses included non-cash share-based compensation expense of \$2.3 million in the first quarter of 2016 as compared to \$0.9 million in the first quarter of 2015.

Total non-cash share-based compensation expense was \$3.7 million for the first quarter of 2016, as compared to \$1.7 million for the first quarter of 2015.

As of March 31, 2016, Prothena had \$474.3 million in cash and cash equivalents and no debt.

As of April 22, 2016, Prothena had approximately 34.3 million ordinary shares outstanding.

The Company expects the full year 2016 net cash burn from operating and investing activities to be \$105 to \$115 million, ending the year with approximately \$388 million in cash (midpoint). The estimated full year 2016 net cash burn from operating and investing activities is primarily driven by an estimated net loss of \$132 to \$149 million, which includes an estimated \$18 million of non-cash share-based compensation expense.

### **Upcoming Investor Conferences**

Members of the senior management team will present and participate in the Bank of America Merrill Lynch 2016 Health Care Conference on May 12, 2016 at 8:40 AM PT in Las Vegas, NV (11:40 AM ET).

A live webcast of the presentation can be accessed through the investor relations section of the Company's website at [www.prothena.com](http://www.prothena.com). Following the live presentation, a replay of the webcast will be available on the Company's website for at least 90 days following the presentation date.

## About Prothena

Prothena Corporation plc is a global, late-stage clinical biotechnology company seeking to fundamentally change the course of progressive diseases with its clinical pipeline of novel therapeutic antibodies. Fueled by its deep scientific understanding built over decades of research in protein misfolding and cell adhesion - the root causes of many serious or currently untreatable amyloid and inflammatory diseases - Prothena has advanced several drug candidates into clinical trials while pursuing discovery of additional novel therapies. Our clinical pipeline of antibody-based product candidates targets a number of potential indications including AL amyloidosis (NEOD001), Parkinson's disease and other related synucleinopathies (PRX002) and inflammatory diseases, including psoriasis (PRX003). For more information, please visit the company's web site at [www.prothena.com](http://www.prothena.com).

## Forward-looking Statements

*This press release contains forward-looking statements. These statements relate to, among other things, the ability of our cash position to support advancement of our clinical pipeline and overall business; the potential for our Phase 2b PRONTO trial to advance our NEOD001 program; the expectation that we will be able to rapidly assess biological activity of PRX003; our potential commercial introduction of NEOD001; the timing of reporting results from the expansion cohort of our Phase 1/2 study, completing enrollment in Phase 3 VITAL study, and reporting results from the PRONTO trial, all for NEOD001; the timing of reporting data from the Phase 1 multiple ascending dose study for PRX002; the timing of reporting data from the Phase 1 single ascending dose study and the Phase 1 multiple ascending dose study for PRX003; our anticipated net cash burn from operating and investing activities for 2016 and expected cash balance at the end of 2016; and our estimated net loss and non-cash share-based compensation expense for 2016. 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) on February 25, 2016 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.*

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

	<b>Three Months Ended March 31,</b>	
	<b>2016</b>	<b>2015</b>
Collaboration revenue	\$ 265	\$ 593
Total revenue	265	593
Operating expenses:		
Research and development	20,493	10,573
General and administrative	7,182	5,049
Total operating expenses	<u>27,675</u>	<u>15,622</u>
Loss from operations	(27,410)	(15,029)
Other income, net	70	93
Loss before income taxes	(27,340)	(14,936)
Provision for income taxes	181	266
Net loss	<u>\$ (27,521)</u>	<u>\$ (15,202)</u>
Basic and diluted net loss per share	\$ (0.81)	\$ (0.55)
Shares used to compute basic and diluted net loss per share	34,026	27,401

**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(unaudited - amounts in thousands)**

	<b>March 31,</b>	<b>December 31,</b>
	<b>2016</b>	<b>2015</b>
<b>Assets</b>		
Cash and cash equivalents	\$ 474,252	\$ 370,586
Other current assets	7,840	6,817
Total current assets	482,092	377,403
Property and equipment, net	3,924	3,862
Other assets	5,292	3,971
Total non-current assets	9,216	7,833
Total assets	\$ 491,308	\$ 385,236
<b>Liabilities and Shareholders' Equity</b>		
Accrued research and development	10,970	12,794
Other current liabilities	12,264	9,422
Total current liabilities	23,234	22,216
Non-current liabilities:	2,294	2,351
Total liabilities	25,528	24,567
Total shareholders' equity	465,780	360,669
Total liabilities and shareholders' equity	\$ 491,308	\$ 385,236

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