



Protagonist Therapeutics Reports Fourth Quarter and Year-End 2016 Financial Results

March 7, 2017

- Phase 2b Trial Underway for PTG-100 in Ulcerative Colitis
- PTG-200 & PTG-300 Expected to Enter the Clinic in 2017

MILPITAS, Calif., March 7, 2017 /PRNewswire/ -- Protagonist Therapeutics, Inc. (NASDAQ: PTGX) today reported its financial results for the fourth quarter and full year ended December 31, 2016 and provided an update on the company's recent achievements.

"In 2016 Protagonist successfully made the transition from a private company to a NASDAQ listed public company, completing an approximately \$83.6 million net raise in an upsized initial public offering," Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer, commented, "The success of the IPO was driven by positive Phase 1 clinical proof-of-concept data for PTG-100, coupled with the current and future potential of our proprietary peptide technology platform and pre-clinical assets PTG-200 and PTG-300."

"In January 2017," continued Dr. Patel, "we dosed our first patient in the PTG-100 Phase 2b clinical trial for ulcerative colitis, for which we anticipate an interim futility analysis in the second half of the year."

Protagonist plans to commence Phase 1 studies for PTG-200 and PTG-300, with top-line, clinical proof-of-concept data for PTG-300 expected in the second half of 2017. All three assets in clinical development have emerged from Protagonist's proprietary peptide technology platform, which the company will continue to utilize to discover new peptide-based drugs.

Additional 2016 and Recent Business Highlights:

- Presented preclinical data on PTG-100 and PTG-200 at Digestive Disease Week (DDW) in May 2016 and at the European Crohn's and Colitis Organization Congress in February 2017.
- Received a Phase 1 Small Business Innovation Research (SBIR) Grant from the National Institute of Heart and Lung Diseases of the National Institutes of Health in July 2016 to fund the development of injectable hepcidin mimetics for the treatment of iron overload disorders.
- Presented two posters detailing Phase 1 clinical and pre-clinical data for PTG-100 at the United European Gastroenterology (UEG) Week in October 2016.
- Received notice for a key patent, No. 9,518,091, issued covering orally stable peptides from the company's most advanced development program in January 2017. This patent together with previously granted U.S. patent No. 9,273,093, provides protection for the company's alpha4beta7 integrin peptide inhibitors, including PTG-100.
- Initiated a global Phase 2b trial for PTG-100 with the goal of enrolling a total of approximately 240 ulcerative patients with moderate to severe active disease. An interim futility analysis is expected to be performed in the second half of 2017. If the outcome is not futile, one or two optimal doses of PTG-100 will be selected for continued randomization of the remaining patients. Top-line results are expected in second half of 2018.

Financial Results

Protagonist reported a net loss of approximately \$37.2 million for the full year 2016, as compared to a net loss of \$14.9 million for the prior year. The company reported a net loss of \$11.2 million for the fourth quarter of 2016, as compared to a net loss of \$5.5 million for the fourth quarter of 2015. The increase in net loss was driven primarily by research and development expenses related to PTG-100 clinical trials and other pre-clinical product candidate studies, and general and administrative expenses for operations.

Research and development expenses for the full year 2016 were \$25.7 million, as compared to \$11.8 million for the prior year. Research and development expenses for the fourth quarter of 2016 were \$8.8 million, as compared to \$4.2 million for the same period in the prior year. Research and development expenses for the fourth quarter included costs related to contract manufacturing, the preparation for and conduct of PTG-100 clinical trials, and preclinical development studies for other product candidates. The expense increases for the fourth quarter were partially offset by an increase of \$2.4 million from our claim under the Australian research and development tax incentive program that includes the recognition of reimbursements of amounts related to non-Australian expenses. Funding under this tax incentive program was completed in 2016, and we expect to receive final payment of \$2.2 million in 2017.

General and administrative expenses for the full year 2016 were \$7.0 million, as compared to \$3.0 million for the prior year. General and administrative expenses for the fourth quarter of 2016 were \$2.6 million, as compared to \$0.8 million for the same period in the prior year. The increase in G&A expense in these periods was due primarily to an increase in professional service fees, salaries and employee-related expense primarily due to an increase in headcount to support the growth of our operations, and other administrative expenses.

Protagonist ended the third quarter of 2016 with \$98.5 million in cash, cash equivalents and investments and ended the fourth quarter of 2016 with \$87.7 million in cash, cash equivalents and investments. The company expects current capital resources will be sufficient to fund operations through PTG-100 Phase 2b top-line data which is expected in the second half of 2018.

About Protagonist Therapeutics Inc.

Protagonist Therapeutics is a clinical-stage biopharmaceutical company with a proprietary technology platform focused on discovering and developing

peptide-based new chemical entities to address significant unmet medical needs. Its primary focus is on developing first-in-class oral peptide drugs that specifically target the same biological pathways for which there are marketed injectable antibody drugs. Compared to injectable antibody drugs, Protagonist's oral peptides offer preferential drug exposure in the gastrointestinal (GI) tissue compartment, the potential for improved safety due to minimal exposure in the blood, improved convenience and compliance, and potentially an opportunity for the earlier introduction of targeted therapy for inflammatory bowel disease (IBD). Protagonist's oral peptide product candidates, PTG-100 and PTG-200, are based on this approach with the potential to transform the existing treatment paradigm for IBD, which includes both ulcerative colitis and Crohn's disease.

PTG-100, a potential first-in-class oral alpha4beta7 integrin antagonist, is being developed initially for moderate-to-severe active ulcerative colitis. PTG-200, a potential first-in-class oral IL-23 receptor antagonist, is being developed initially for Crohn's disease and is currently in IND-enabling studies.

The company has a peptide technology platform that enables the discovery of oral and injectable peptides that can be utilized against a diverse set of targets and diseases including, but not restricted to GI disease. In addition to PTG-100 and PTG-200, the company is also engaged in the discovery and development of an injectable hepcidin mimetic, PTG-300, which is currently in IND-enabling studies. PTG-300 has potential utility for the treatment of iron overload disorders such as beta-thalassemia, which may qualify PTG-300 for orphan drug designation.

Protagonist is headquartered in Milpitas, California with its pre-clinical and clinical development staff in California, and discovery operations in both California and Brisbane, Queensland, Australia. For further information, please visit <http://www.protagonist-inc.com>.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our intentions or current expectations concerning, among other things, the potential for our programs, plans, timing and the availability of results of our clinical trials, enrollment in our clinical trials, capital resources, the possibility of obtaining orphan drug designation, and the potential for eventual regulatory approval of our product candidates. In some cases you can identify these statements by forward-looking words such as "may," "will," "continue," "expects," or the negative or plural of these words or similar expressions. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ materially from those anticipated, including, but not limited to, our history of net operating losses, our reliance on third parties and uncertainty regarding our ability to achieve profitability, our ability to develop and commercialize our product candidates, our ability to use and expand our programs to build a pipeline of product candidates, our ability to obtain and maintain regulatory approval of our product candidates, our ability to operate in a competitive industry and compete successfully against competitors that have greater resources than we do, and our ability to obtain and adequately protect intellectual property rights for our product candidates. We discuss many of these risks in greater detail under the heading "Risk Factors" contained in our Annual Report on Form 10-K for the year ended December 31, 2016, to be filed with the Securities and Exchange Commission concurrently herewith. Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

PROTAGONIST THERAPEUTICS, INC.

Consolidated Statements of Operations (In thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
	(Unaudited)			
Operating expenses:				
Research and development	\$ 8,823	\$ 4,193	\$ 25,705	\$ 11,831
General and administrative	2,574	808	6,961	2,963
Total operating expenses	11,397	5,001	32,666	14,794
Loss from operations	(11,397)	(5,001)	(32,666)	(14,794)
Interest income	149	17	242	19

Change in fair value of redeemable convertible preferred stock tranche and warrant liabilities	—	(509)	(4,719)	(83)
Other expense	—	—	(34)	—
Net loss	<u>\$ (11,248)</u>	<u>\$ (5,493)</u>	<u>\$ (37,177)</u>	<u>\$ (14,858)</u>
Net loss attributable to common stockholders	<u>\$ (11,248)</u>	<u>\$ (5,533)</u>	<u>\$ (37,735)</u>	<u>\$ (14,933)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.67)</u>	<u>\$ (20.31)</u>	<u>\$ (5.80)</u>	<u>\$ (59.32)</u>
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	<u>16,718,242</u>	<u>272,409</u>	<u>6,501,796</u>	<u>251,717</u>

PROTAGONIST THERAPEUTICS, INC.
Selected Consolidated Balance Sheet Data
(In thousands)

	December 31,	
	2016	2015
Consolidated Balance Sheet Data:		
Cash, cash equivalents and available-for-sale securities	\$ 87,749	\$ 11,923
Working capital	76,809	11,080
Total assets	93,990	14,845
Accumulated deficit	(64,593)	(27,416)
Redeemable convertible preferred stock tranche liability	—	1,643
Redeemable convertible preferred stock warrant liability	—	480
Redeemable convertible preferred stock	—	36,996
Total stockholders' equity (deficit)	87,555	(27,400)

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/protagonist-therapeutics-reports-fourth-quarter-and-year-end-2016-financial-results-300419686.html>

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