Protagonist Therapeutics Reports First Quarter 2019 Financial Results

May 8, 2019

-- PTG-200 collaboration agreement with Janssen Biotech expanded to include second generation oral IL-23 receptor antagonists; expanded agreement triggers $25 million milestone payment to Protagonist --

-- Protagonist appoints Samuel Saks, M.D., as Chief Medical Officer and Suneel Gupta, Ph.D., as Chief Development Officer --

-- Preliminary results from the Phase 2 TRANSCEND study of PTG-300 for the treatment of beta thalassemia expected in the second half of 2019 --

-- Initial results from the Phase 1 study of PN-943 expected in the second quarter of 2019 --

NEWARK, Calif., May 8, 2019 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today reported its financial results for the first quarter ended March 31, 2019. The Company also announced changes to the executive management team, with the appointment of Samuel Saks, M.D., as Chief Medical Officer. In addition, Suneel Gupta, Ph.D., current Executive Vice President of Clinical Operations and Pharmacology, has been promoted to the role of Chief Development Officer.

"We are pleased to have Dr. Saks expand his involvement with Protagonist as our programs transition to mid-to-late-stage development," commented Dinesh Patel, Ph.D., President and Chief Executive Officer of Protagonist Therapeutics. "His contributions as Chief Development Officer have been invaluable over the past year as multiple programs have progressed to different stages of development. In addition, we welcome Dr. Gupta to the senior executive team, bringing an abundance of experience across all areas of pharmaceutical product development as our programs continue to mature in the development pipeline. These updates to management serve to broaden and strengthen our clinical development capabilities at a critical inflection point as we move forward with the development of our three clinical candidates, PTG-300, PTG-200 and PN-943. We are pleased to report that we are well financed to support all of our programs through the end of 2020."

In conjunction with the appointment of Dr. Saks to his new role at the Company, Richard Shames, M.D., Chief Medical Officer of Protagonist, will transition to the role of clinical advisor.

Dr. Patel continued, "We are grateful for Dr. Shames' involvement over the past several years as we have worked together to bring multiple programs from preclinical into clinical development, and are pleased to have him participate as a clinical advisor as we continue to update and expand the management team."

Product Development Update:

PTG-300

- In January, Protagonist announced the initiation of dosing in the Phase 2 TRANSCEND study, a single-arm, open label, global study of injectable hepcidin mimetic PTG-300 in the treatment of patients with transfusion-dependent or non-transfusion dependent beta thalassemia. Preliminary results from this Phase 2 trial are expected in the second half of 2019.
- The Company expects to begin clinical development of PTG-300 in a second indication in the second half of 2019.

PTG-200

- As recently announced, the PTG-200 collaboration agreement with Janssen Biotech has been expanded to include second generation oral IL-23 receptor antagonists, with Protagonist receiving a $25 million milestone payment triggered by the expanded agreement.
- Protagonist and Janssen Biotech are working towards filing a U.S. IND application to support a global Phase 2 clinical study in patients with Crohn's disease. This IND filing is expected in the second quarter of 2019.

PN-943

- Protagonist announced the initiation of dosing in a Phase 1 study of PN-943, which is being developed as a potential novel oral therapy for patients with inflammatory bowel disease. The study will evaluate safety, pharmacokinetics, and pharmacodynamic readouts of target engagement as measured by blood receptor occupancy in healthy volunteers. Top-line results from this Phase 1 study are expected in the second quarter of 2019.
- The PN-943 Phase 1 data is expected to provide information that will inform the design of a Phase 2 study of PN-943 in patients with ulcerative colitis, with an expected U.S. IND filing in late 2019.
- Preclinical research findings describing the properties of PN-943 have been selected for an oral presentation in a Distinguished Abstract Plenary session on Sunday, May 19, 2019, at the Digestive Diseases Week Conference in San Diego.

Financial Results

Protagonist reported a net loss of $14.1 million for the first quarter of 2019, as compared to a net loss of $7.7 million for the same period of 2018. The increase in net loss was driven primarily by a decrease in license and collaboration revenue recognized during the first quarter of 2019. The net loss for the first quarter of 2019 includes non-cash stock-based compensation of $2.0 million, as compared to $1.2 million for the same period of 2018.

License and collaboration revenue, comprised both of revenue recognition relating to the $50 million upfront payment received from Janssen Biotech in 2017 and the services performed under the collaboration agreement, was $1.6 million for the first quarter of 2019 compared to $10.8 million for the same period of 2018. The year over year decrease in license and collaboration revenue is primarily related to the Company approaching, during 2019, the end of the revenue recognition phase of the $50 million upfront payment received from Janssen Biotech in 2017. The Company continued to deliver compound supply services under the Janssen collaboration agreement in the first quarter of 2019.

R&D expenses for the first quarter of 2019 were $12.4 million, which decreased from $15.4 million for the same period of the prior year. The decrease in R&D expenses was primarily due to a decrease in costs on our former development candidate PTG-100 and decreased expenditures related to our shared expenses on PTG-200 under the Janssen collaboration agreement, offset by increased costs related to moving forward our product candidates PTG-300 and PN-943. These R&D costs are primarily related to contract manufacturing and the preparation for and conduct of clinical trials. R&D expenses for the quarter also include an increase in salaries and employee-related expenses due to an increase in stock-based compensation expense.

G&A expenses for the first quarter of 2019 were $3.8 million, as compared to $3.6 million for the same period in the prior year. The increase in G&A expense was due primarily to increases related to supporting the growth of our operations and stock-based compensation expense.

Protagonist ended the first quarter of 2019 with $112.5 million in cash, cash equivalents and investments. Protagonist expects to have sufficient financial resources to fund operations to the end of 2020.

About Protagonist Therapeutics, Inc.

Protagonist Therapeutics is a clinical stage biopharmaceutical company that utilizes a proprietary technology platform to discover and develop novel peptide-based drugs to transform existing treatment paradigms for patients with significant unmet medical needs. PTG-300 is an injectable hepcidin mimetic for the potential treatment of anemia and iron overload related rare blood diseases with an initial focus on beta thalassemia. PTG-200 is an oral gut-restricted interleukin-23 receptor antagonist in development for the treatment of inflammatory bowel disease. The Company has entered into a worldwide license and collaboration agreement with Janssen Biotech for the clinical development of PTG-200. PN-943 is an oral, gut-restricted alpha-4-beta-7 integrin antagonist peptide in development for the treatment of inflammatory bowel disease.

Protagonist is headquartered in Newark, California, with pre-clinical and clinical staff in California and discovery operations in both California and Brisbane, Queensland, Australia. For further information, please visit 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 clinical programs, our collaborations and milestone payments we may receive under them, the initiation and availability of results of our clinical trials, our research and development plans, the utility of our intellectual property, and the sufficiency of our financial resources. In some cases, you can identify these statements by forward-looking words such as "anticipate," "believe," "may," "will," "expect," 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 ability to develop and commercialize our product candidates, our ability to earn milestone payments under our collaboration agreement with Janssen, 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. Additional information concerning these and other risk factors affecting our business can be found in our periodic filings with the Securities and Exchange Commission, including under the heading "Risk Factors" contained in our Quarterly Report on Form 10-Q for the three months ended March 31, 2019, to be filed with the Securities and Exchange Commission. 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 March 31,	
	2019	**2018**
License and collaboration revenue - related party	$ 1,560	$ 10,781
Operating expenses:		
Research and development	12,444	15,368
General and administrative	3,764	3,642
Total operating expenses	16,208	19,010
Loss from operations	(14,648)	(8,229)
Interest income	728	568
Loss before income tax expense	(13,920)	(7,661)

Income tax expense	(183)	--
Net loss	$ (14,103)	$ (7,661)
Net loss per share, basic and diluted	$ (0.58)	$ (0.36)
Weighted-average shares used to compute net loss per share, basic and diluted	24,297,576	21,112,393

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

	March 31, 2019	December 31, 2018
Consolidated Balance Sheet Data:		
Cash, cash equivalents and available-for-sale securities	$ 112,546	$ 128,853
Working capital	$ 98,496	$ 111,345
Total assets	$ 132,248	$ 139,472
Deferred revenue – related party	$ 7,001	$ 8,223
Accumulated deficit	$ (154,577))	$ (140,474))
Total stockholders' equity	$ 100,825	$ 112,515

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