Protagonist Therapeutics Reports First Quarter Financial Results and Provides Corporate Update

May 7, 2020

-- Company selects the polycythemia vera indication for pivotal development of PTG-300 based on robust clinical responses --

-- Revised and focused development plans now provide sufficient capital to fund operations through mid-2022 --

-- Protagonist to host a conference call today to provide a corporate update, and details of initial Phase 2 polycythemia vera results to be presented by Ronald Hoffman, M.D., Director of the Myeloproliferative Diseases Program at The Icahn School of Medicine at Mount Sinai --

NEWARK, Calif., May 7, 2020 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today reported its financial results for the first quarter ended March 31, 2020, and provided an update on clinical development programs.

"Based on the highly promising and consistent clinical responses achieved to date, we are pleased to announce polycythemia vera as the first indication for a pivotal study of PTG-300," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "With an orphan drug development regulatory path forward, we are focused on rapidly advancing PTG-300 as a first-in-class non-cytoreductive hepcidin hormone mimetic agent for this indication with significant unmet need. With a highly focused development effort forward with PTG-300 for polycythemia vera, and deferring PN-943 Phase 2 initiation due to the current COVID-19 environment, we have reduced our operational expenditures and now have an additional six months of cash runway estimated to extend through mid-2022."

Product Development Update

PTG-300: Injectable Hepcidin Mimetic

- Initial Phase 2 results in patients with polycythemia vera from an ongoing study demonstrated that treatment with PTG-300 at individualized doses ranging from 10 mg to 80 mg for up to 28 weeks controlled hematocrit levels. All patients were phlebotomy free (except a single phlebotomy due to an unintended dose interruption in a patient who remains on study). Administration of PTG-300 was well tolerated and the safety profile was generally similar with results of prior studies, with injection site reactions and bruise as the only adverse events related to or possibly related to treatment. Results are available as of the May 1, 2020, cutoff date.
- The results of the PTG-300 beta-thalassemia Phase 2 study will be presented at an upcoming medical conference in the second quarter of 2020.
- Protagonist will redirect the majority of its PTG-300 efforts to the polycythemia vera indication, while also continuing its exploration of PTG-300 in hereditary hemochromatosis. The Company is discontinuing clinical development for PTG-300 in beta-thalassemia and myelodysplastic syndromes.

PTG-200 (JNJ-67864238): Oral IL-23 Receptor Antagonist for Inflammatory Bowel Disease

- In collaboration with Janssen Biotech, we initiated a Phase 2 global study for PTG-200 (or JNJ-67864238) in moderate-to-severe Crohn's disease in the fourth quarter of 2019. Because of the global COVID-19 pandemic, guidance has been currently suspended on a timeline for study completion.

PN-943: Oral Alpha-4-Beta-7 Integrin Antagonist for Inflammatory Bowel Disease

- A Phase 2 study of PN-943 in approximately 150 patients with moderate-to-severe ulcerative colitis is currently planned.
- In light of the global COVID-19 pandemic, Protagonist continues to review all aspects of the planned Phase 2 study and is currently suspending guidance on a timeline for study initiation. The Company is maintaining readiness to initiate the study as soon as conditions allow for safe accrual of subjects for the global study.

Financial Results

- **Cash, Cash Equivalents and Marketable Securities:** Cash, cash equivalents and marketable securities as of March 31, 2020, were $117.5 million. Due to the focusing of efforts on polycythemia vera and the delay in PN-943 trial initiation caused by the ongoing global COVID-19 pandemic and a related internal reorganization, the company believes its adjusted operating plans now provide sufficient financial resources from its cash, cash equivalents, marketable securities and access to its debt facility to fund its currently planned operating and capital expenditures through mid-2022. The company will continue to monitor events closely and may further adjust its operating plans as warranted.
- **License and Collaboration Revenue:** License and collaboration revenue of $3.6 million for the first quarter of 2020 increased in comparison to $1.6 million reported for the same period of 2019. License and collaboration revenue is generally earned over time as services are provided under the collaboration.
- **Research and Development ("R&D") Expenses:** R&D expenses for the first quarter 2020 were $18.8 million as

compared to $12.4 million for the same period of 2019. The increase was primarily due to increased clinical development costs related to PTG-300, PN-943 and our IL-23 receptor antagonist collaboration with Janssen Biotech to develop PTG-200 and the related research collaboration efforts.

- **General and Administrative ("G&A") Expenses:** G&A expenses for the first quarter 2020 were $4.6 million, as compared to $3.8 million for the same period of 2019. The increase was primarily due to increases in salaries, employee-related expenses and professional services to support the growth in our operations.
- **Net Loss:** The first quarter 2020 net loss was $20.1 million, or a net loss of $0.72 per share, as compared to a net loss of $14.1 million, or a net loss of $0.58 per share, for the same period of 2019.

Conference Call and Webcast Information

Protagonist will host a conference call at 5 p.m. EDT / 2 p.m. PDT today to provide a corporate update. Ronald Hoffman, M.D., Director of the Myeloproliferative Diseases Program at The Icahn School of Medicine at Mount Sinai, will join the call to present initial results for PTG-300 in polycythemia vera. To access the live call, dial 1-844-515-9178 (U.S./Canada) or 1-614-999-9313 (international) and refer to conference ID number 4597494. A live and archived webcast will also be accessible in the Investors section of the Company's website at www.protagonist-inc.com.

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 therapeutics to address significant unmet medical needs and transform existing treatment paradigms for patients. The Company currently has three clinical-stage assets. PTG-300 is an injectable hepcidin mimetic in development for the treatment of polycythemia vera and hereditary hemochromatosis. PTG-200 is an orally delivered, gut-restricted, interleukin-23 receptor specific antagonist peptide in development for the treatment of inflammatory bowel disease, with Crohn's disease as the initial indication. The Company has a worldwide license and collaboration agreement with Janssen Biotech, Inc., for the development of PTG-200. PN-943 is an orally delivered, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide in development for the treatment of inflammatory bowel disease, with ulcerative colitis as the initial targeted indication.

Protagonist is headquartered in Newark, California. 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 ongoing clinical programs, our plans for future clinical trials, the impact of the global COVID-19 pandemic, the potential of PTG-300 as a possible treatment for polycythemia vera, beta-thalassemia and hereditary hemochromatosis, the potential of PTG-200 and PN-943 as possible treatments for inflammatory bowel disease, the initiation and availability of results of our clinical trials and the sufficiency of our financial resources, our ability to fund our clinical trials, the initiation of and enrollment of patients in our clinical trials, the results of clinical trials and the outlook for our other programs. In some cases, you can identify these statements by forward-looking words such as "plan," "estimate," "will," "potential," 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 Biotech, 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 and risks related to the global COVID-19 pandemic and actions taken to slow its spread. 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 period ended March 31, 2020, 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)
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
License and collaboration revenue - related party	$ 3,647	$ 1,560
Operating expenses:		
Research and development [1]	18,768	12,444
General and administrative [1]	4,576	3,764
Total operating expenses	23,344	16,208
Loss from operations	(19,697)	(14,648)
Interest income	526	731
Interest expense	(243)	-
Other income (expense), net	(490)	(3)
Loss before income taxes	(19,904)	(13,920)
Income tax (expense)	(176)	(183)

Net loss	$	(20,080)	$	(14,103)
Net loss per common share, basic and diluted	$	(0.72)	$	(0.58)
Weighted-average shares used to compute net loss per share, basic and diluted		27,703,918		24,297,576

(1) Amounts include non-cash stock-based compensation expense as follows (in thousands):

	Three Months Ended March 31,	
Stock-based compensation	**2020**	**2019**
Research and development	$ 1,066	$ 1,122
General and administrative	982	857
Total stock-based compensation expense	$ 2,048	$ 1,979

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

	March 31, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	$ 117,513	$ 133,017
Working capital	$ 89,614	$ 109,905
Total assets	$ 134,901	$ 154,917
Long-term debt, net	$ 9,832	$ 9,794
Deferred revenue - related party	$ 39,045	$ 41,530
Accumulated deficit	$ (237,741)	$ (217,661)
Total stockholders' equity	$ 62,666	$ 79,964

View original content to download multimedia:http://www.prnewswire.com/news-releases/protagonist-therapeutics-reports-first-quarter-financial-results-and-provides-corporate-update-301055215.html

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