Protagonist Therapeutics Reports Second Quarter Financial Results and Provides Corporate Update

August 6, 2020

-- Company to host webinar highlighting the PTG-300 program market opportunity in polycythemia vera --

-- PTG-300 received U.S. Food and Drug Administration (FDA) Orphan Drug Designation for the treatment of polycythemia vera --

-- Financial resources expected to support operations through mid-2023 --

NEWARK, Calif., Aug. 6, 2020 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq: PTGX) today reported financial results for the second quarter ended June 30, 2020, and provided an update on clinical development programs.

"We have succeeded in bringing three differentiated candidates from *de novo* discovery into Phase 2 development," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "Each of these candidates has unique attributes that address specific unmet needs in diverse diseases, such as blood disorders with PTG-300 and inflammatory bowel disease with PTG-200 and PN-943. The hepcidin mimetic PTG-300 makes use of the iron homeostasis mechanism of a natural hormone and has demonstrated potential in the treatment of polycythemia vera. We expect to initiate a pivotal study for PTG-300 in 2021 after discussions with the regulatory agencies. PN-943 and PTG-200 are both oral, gut-restricted candidates for the potential treatment of inflammatory bowel disease. PTG-200 is an IL-23 receptor antagonist partnered with Janssen and is currently in a Phase 2 Crohn's study. We recently initiated screening of patients for our Phase 2 study of PN-943 in ulcerative colitis. Finally, we are well financed and recently raised $122 million through a successful secondary offering and use of our ATM program, which enables us to support planned operations through mid-2023."

Product Development and Corporate Update

PTG-300: Injectable Hepcidin Mimetic for Polycythemia Vera and Other Blood Disorders

- Initial Phase 2 results reported in May 2020 in patients with polycythemia vera demonstrated clinically meaningful dose related control of hematocrit levels on individual patient basis.
- In June 2020, PTG-300 received U.S. Food and Drug Administration (FDA) Orphan Drug Designation for the treatment of polycythemia vera.
- Protagonist plans to host a webinar featuring presentations on clinical needs and market research on the potential opportunity for PTG-300 in polycythemia vera. The "PTG-300 Opportunity Update" webinar will be conducted Sept. 11, 2020. Details for participation will be publicly announced prior to the event.

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

- Protagonist has initiated screening of prospective subjects in a global, randomized, double-blind, placebo-controlled Phase 2 study (the "IDEAL Study") evaluating safety, tolerability and efficacy of PN-943 in approximately 150 patients with moderate to severe active ulcerative colitis. Patients will be randomized in one of three arms (150 mg twice daily, 450 mg twice daily, or placebo) for 12 weeks of oral dosing followed by an extended treatment period of 40 weeks. During the extended treatment period all subjects will receive PN-943. The primary endpoint of the study is proportion of subjects achieving clinical remission at week 12 (as defined by rectal bleeding, stool frequency and endoscopic subscores of the Adapted Mayo Score) in the 450 mg twice daily treatment arm as compared to placebo. Secondary endpoints include additional clinical and safety assessments, as well as pharmacokinetic and pharmacodynamic measurements, and biomarker measurements related to disease activity.

Oral IL-23 Receptor Antagonists (Janssen Biotech and Protagonist Collaboration)

- Janssen Biotech is conducting a global Phase 2 study of PTG-200 (or JNJ-67864238) in moderate-to-severe Crohn's disease.
- Joint research efforts are underway to identify second-generation oral IL-23 receptor antagonists for multiple indications.

Financial Update

- During May 2020, the Company successfully raised $105.7 million net of underwriting and offering expenses in an oversubscribed secondary offering issuing 8,050,000 shares at $14.00 per share.
- During the second quarter of 2020, the Company issued 1.2 million shares through its at-the-market (ATM) program and raised $16.8 million, at an average price of $14.02 per share.

Financial Results

- **Cash, cash equivalents and marketable securities** as of June 30, 2020, were $208.7 million. Protagonist estimates 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-2023.
- **License and collaboration revenues** were $6.2 million and $9.9 million for the second quarter and six months ended 2020, respectively, in comparison to $(8.2) million and $(6.6) million reported for the same periods of 2019. The increase in revenue was due mainly to the previously reported 2019 one-time cumulative adjustment related to the application of revenue recognition principles following the May 2019 amendment of the Janssen Biotech collaboration agreement that had reduced revenue by $9.4 million for the three and six months ended June 30, 2019.
- **Research and Development ("R&D") expenses** for the three and six months ended June 30, 2020, were $20.3 million and $39.0 million, respectively, as compared to $19.4 million and $31.8 million for the same periods of 2019. These variances were primarily due to increased activities in advancing our ongoing clinical trial for polycythemia vera with PTG-300, preparedness for PN-943 Phase 2 study in ulcerative colitis, and our IL-23 receptor antagonist research collaboration activities with Janssen Biotech.
- **General and Administrative ("G&A") expenses** for the three and six months ended June 30, 2020, were $4.2 million and $8.8 million, respectively, as compared to $3.9 million and $7.6 million for the same periods of 2019. The increases were primarily due to increases in salaries, insurance expense and professional services to support the growth in our operations.
- **Net loss** for the three and six months ended June 30, 2020, was $19.4 million and $39.5 million or a net loss of $0.59 per share and $1.31 per share, respectively, as compared to a net loss of $29.2 million and $43.3 million, or a net loss of $1.18 per share and $1.77 per share, for the same periods of 2019.

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 other blood disorders. 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 potential of PTG-300 as a possible treatment for polycythemia vera and other blood disorders, the potential of PTG-200 and PN-943 as possible treatments for inflammatory bowel disease, the potential of a pivotal study for PTG-300 in 2021, the potential of our Phase 2 study of PN-943 in ulcerative colitis, the initiation and availability of results of our clinical trials, 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 "potential," "expect," "plan," "estimate," "will," 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 June 30, 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.
Selected Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	June 30, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	$ 208,665	$ 133,017
Working capital	182,106	109,905
Total assets	224,980	154,917
Long-term debt, net	--	9,794
Deferred revenue - related party	34,014	41,530
Accumulated deficit	(257,162)	(217,661)
Total stockholders' equity	167,485	79,964

PROTAGONIST THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(Amounts in thousands except share and per share data)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenue:				
License and collaboration revenue - related party	$ 6,217	$ (8,189)	$ 9,864	$ (6,629)
Operating expenses:				
Research and development [1]	20,257	19,355	39,025	31,799
General and administrative [1]	4,177	3,863	8,753	7,627
Total operating expenses	24,434	23,218	47,778	39,426
Loss from operations	(18,217)	(31,407)	(37,914)	(46,055)
Interest income	207	641	733	1,372
Interest expense	(209)	--	(452)	--
Loss on early repayment of debt	(585)	--	(585)	--
Other income (expense), net	512	(37)	22	(39)
Loss before income taxes	(18,292)	(30,803)	(38,196)	(44,722)
Income tax (expense) benefit	(1,129)	1,629	(1,305)	1,445
Net loss	$ (19,421)	$ (29,174)	$ (39,501)	$ (43,277)
Net loss per common share, basic and diluted	$ (0.59)	$ (1.18)	$ (1.31)	$ (1.77)
Weighted-average shares used to compute net loss per share, basic and diluted	32,799,691	24,662,779	30,251,805	24,481,186

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

Stock-based compensation	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Research and development	$ 1,026	$ 977	$ 2,092	$ 2,100
General and administrative	970	1,036	1,952	1,892
Total stock-based compensation expense	$ 1,996	$ 2,013	$ 4,044	$ 3,992

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