Protagonist Therapeutics Reports Second Quarter 2019 Financial Results

August 7, 2019

-- Preliminary Phase 2 results for hepcidin mimetic PTG-300 in beta-thalassemia are expected in the fourth quarter of 2019 --

-- Phase 2 study of PTG-300 in polycythemia vera expected to begin in the third quarter of 2019; studies in hereditary hemochromatosis and myelodysplastic syndrome planned for early 2020 --

-- Phase 1 studies with oral alpha-4-beta-7 integrin antagonist PN-943 in normal healthy volunteers are complete --

-- Phase 2 U.S. Investigational New Drug (IND) application for Crohn's disease filed by partner Janssen Biotech for oral IL-23 receptor antagonist PTG-200 --

NEWARK, Calif., Aug. 7, 2019 /PRNewswire/ -- Protagonist Therapeutics, Inc. (Nasdaq:PTGX) today reported financial results for the second quarter ended June 30, 2019, and provided a corporate update.

"We continue to make great progress in advancing our three clinical assets in diverse disease areas and are pleased with our cash runway scenario, which we expect will provide operating capital through mid-2021," commented Dinesh V. Patel, Ph.D., Protagonist President and Chief Executive Officer. "In addition to the ongoing study of hepcidin mimetic PTG-300 in patients with beta-thalassemia, we expect to initiate a Phase 2 study in the third quarter in patients with polycythemia vera (PV), a rare myeloproliferative disease with limited treatment options. Given the central role of hepcidin in iron homeostasis and erythropoiesis, we view PTG-300 as a one product portfolio with potential applications in multiple blood disorders. We also intend to initiate a Phase 2 study in patients with hereditary hemochromatosis, and we expect that an investigator-sponsored trial in patients with myelodysplastic syndromes will begin in early 2020. These indications rely on different aspects of iron biology that comprise the central mechanism of PTG-300 and offer the advantage of allowing evaluation in small clinical studies with objective endpoints. We are also pleased with the successful completion of the Phase 1 study of our oral alpha-4-beta-7 integrin antagonist PN-943 in normal healthy volunteers, and are advancing PN-943 toward a Phase 2 study in patients with ulcerative colitis. Finally, our oral IL-23 receptor antagonist PTG-200, partnered with Janssen, is moving forward in a Phase 2 study in patients with Crohn's disease."

Corporate and Product Development Updates:

Financing

- During the second quarter of 2019, the Company issued 921,684 shares through its at-the-market (ATM) program and raised $10.5 million, at an average of $11.44 per share.
- The Company also reported sales of an additional 1.2 million shares through its ATM program during July 2019, raising $15.0 million, or $12.64 per share.
- The additional funding is expected to extend the Company's cash runway through mid-2021 as it advances its three clinical programs.
- As of July 31, 2019, the Company had $22.1 million remaining available for sale under its ATM financing facility.

PTG-300

- Protagonist is conducting the Phase 2 TRANSCEND study, a single-arm, open label, study of PTG-300, an injectable hepcidin mimetic, in the treatment of patients with transfusion-dependent as well as non-transfusion dependent beta-thalassemia. Initial results from this Phase 2 trial are expected in the fourth quarter of 2019, with final topline data expected in the first half of 2020.
- Protagonist plans to initiate a Phase 2 study of PTG-300 in patients with polycythemia vera in the third quarter of 2019.
- The Company is working toward the initiation of a clinical study in early 2020 of PTG-300 in the treatment of hereditary hemochromatosis, a third indication of development for PTG-300.
- An investigator-sponsored study of PTG-300 in patients with myelodysplastic syndromes is also expected to begin in early 2020.

PTG-200

- In May 2019, Protagonist expanded its collaboration with Janssen Biotech to include the discovery of second generation oral IL-23 receptor antagonists, with Protagonist receiving a $25 million milestone payment following the signing of the expanded agreement. Protagonist also received research funding supporting full-time equivalent employees.
- Protagonist and Janssen are jointly conducting the development of PTG-200 through completion of a Phase 2 proof-of-concept study in Crohn's disease. Protagonist and Janssen Biotech completed the filing of a U.S. Investigational New Drug (IND) application to support the global Phase 2 clinical study with initiation expected in the fourth quarter of 2019.

PN-943

- In May 2019, Protagonist announced results of the single ascending dose part of the first clinical study of PN-943. The Company also recently announced results from the multiple ascending dose part of the study. Administration of PN-943 was found to be safe and well tolerated, and results of target engagement as measured by blood receptor occupancy were supportive of the higher potency of PN-943 as compared to the first generation antagonist, PTG-100. The PN-943 Phase 1 data has guided the design of a Phase 2 study of PN-943 in patients with ulcerative colitis, with study initiation expected in early 2020.
- Preclinical and early clinical research findings from the single ascending dose study describing the properties of PN-943, including high potency relative to PTG-100, were detailed in an oral presentation in May 2019 at the Digestive Diseases Week Conference in San Diego.

Financial Results

Protagonist reported a net loss of $29.2 million and $43.3 million, respectively, for the second quarter and first six months of 2019, as compared to a net loss of $8.7 million and $16.3 million, respectively, for the same periods of 2018. The increase in net loss for both the second quarter and year-to-date periods was driven primarily by the application of revenue accounting principles following the May 2019 Amendment to the Janssen collaboration agreement. The Company reported an adjustment to revenue of $(8.2) million which decreased the booked license and collaboration revenue in the second quarter. Application of the accounting principles required the Company to re-assess overall timelines as well as re-estimate completed and remaining services following the Collaboration Agreement amendment, leading to the revenue adjustment. The Company also determined that the accounting transaction price had increased to $109.2 million as of June 30, 2019, following the Amendment, from $60.6 million as of March 31, 2019. This has been influenced predominantly by the $25 million milestone payment received from Janssen in the second quarter along with additional research funding and other research and development (R&D) services. The remaining revenue of $64.9 million will be recognized as the Company performs services related to PTG-200 development as well as new services related to the R&D activities for second generation product candidates.

The net loss for the second quarter and first six months of 2019 includes non-cash stock-based compensation of $2.0 million and $4.0 million, respectively, as compared to $1.6 million and $2.8 million, respectively, for the same periods of 2018.

Amounts reported in the category of license and collaboration revenue were $(8.2) million and $(6.6) million for the second quarter and first six months of 2019, respectively, and contained the cumulative catch-up revenue accounting adjustment following the amendment to the Janssen Collaboration Agreement. This is compared to license and collaboration revenue of $11.7 million and $22.5 million for the second quarter and first six months of 2018, respectively.

R&D expenses for the second quarter and first six months of 2019 were $19.4 million and $31.8 million, respectively, as compared to $17.7 million and $33.1 million, respectively, for the same periods of 2018. The increases in R&D expenses in the second quarter from the same period a year ago are primarily due to increased costs related to preparation for and conduct of clinical trials for our product candidates PTG-300 and PN-943. R&D expenses for the quarter also included an increase in salaries and employee-related expenses.

G&A expenses for the second quarter and first six months of 2019 were $3.9 million and $7.6 million, respectively, as compared to $3.2 million and $6.8 million, respectively, for the same periods of 2018. The increases in G&A expenses were primarily due to increases in salaries and employee-related expenses primarily due to an increase in headcount and consulting and professional services expenses to support growth in operations.

Protagonist ended the second quarter of 2019 with $126.1 million in cash, cash equivalents and investments. Protagonist forecasts having sufficient financial resources to fund operations through mid-2021.

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 in development for the treatment of iron overload anemia and related rare blood diseases. PTG-300 is currently in a global Phase 2 study in beta-thalassemia. PTG-200 is an oral, gut-restricted interleukin-23 receptor specific antagonist peptide in clinical development for the potential treatment of inflammatory bowel disease. The Company has a worldwide license and collaboration agreement with Janssen Biotech for the clinical development of PTG-200 and a Phase 2 study in Crohn's disease is expected in fourth quarter of 2019. PN-943 is an oral, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide in clinical development for the potential treatment of inflammatory bowel disease, with ulcerative colitis as the initial intended indication.

Protagonist is headquartered in Newark, California. 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, our cash runway and the availability of results of our clinical trials. 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. 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 and six months ended June 30, 2019, 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 June 30,		Six Months Ended June 30,	
	2019	**2018**	**2019**	**2018**
License and collaboration revenue - related party	$ (8,189)	$ 11,674	$ (6,629)	$ 22,455
Operating expenses:				
Research and development	19,355	17,735	31,799	33,103
General and administrative	3,863	3,178	7,627	6,820
Total operating expenses	23,218	20,913	39,426	39,923
Loss from operations	(31,407)	(9,239)	(46,055)	(17,468)
Interest income	604	576	1,333	1,144
Net loss before income tax benefit	(30,803)	(8,663)	(44,722)	(16,324)
Income tax benefit	1,629	--	1,445	--
Net loss	$ (29,174)	$ (8,663)	$ (43,277)	$ (16,324)
Net loss per share, basic and diluted	$ (1.18)	$ (0.41)	$ (1.77)	$ (0.77)
Weighted-average shares used to compute net loss per share, basic and diluted	24,662,779	21,207,234	24,481,186	21,160,076

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

	June 30, 2019	December 31, 2018
Consolidated Balance Sheet Data:		
Cash, cash equivalents and available-for-sale securities	$ 126,101	$ 128,853
Working capital	$ 103,998	$ 111,345
Total assets	$ 148,105	$ 139,472
Deferred revenue – related party	$ 41,567	$ 8,223
Accumulated deficit	(183,751)	$ (140,474)

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