Protagonist Reports First Quarter 2021 Financial Results and Provides Corporate Update

May 4, 2021

NEWARK, Calif., May 4, 2021 /PRNewswire/ -- Protagonist Therapeutics (Nasdaq: PTGX) ("Protagonist" or the "Company") today reported financial results for the first quarter of 2021 ended March 31, 2021 and provided a corporate update.

"Our progress this quarter affirms the strength of our pipeline and execution capabilities," said Dinesh Patel, PhD, Protagonist's President and Chief Executive Officer. "For our lead drug candidate, rusfertide in polycythemia vera, we have completed enrollment for our Phase 2 study and confirmed the registrational path forward based on recent engagement with both U.S. and European regulators. We look forward to providing an interim update from our ongoing Phase 2 study at a major medical conference in the second quarter of 2021."

Dr. Patel continued, "We are very pleased with the rate of enrollment in our ongoing Phase 2 study of the oral alpha-4-beta-7-integrin antagonist PN-943. For our oral IL-23 receptor antagonists, we expect to dose the first subject in the Phase 1 study of PN-232 in the second quarter of 2021 and intend to complete both this trial and the Phase 1 trial of PN-235 during the second half of 2021. There is excellent movement forward across our full portfolio, driven by our commitment to patients in need of new and better therapeutic options."

PRODUCT DEVELOPMENT AND CORPORATE UPDATE

Disorders of Red Blood Cells and Iron Regulation

Rusfertide (PTG-300)
Investigational, injectable, hepcidin mimetic discovered through our peptide technology platform. Hepcidin is a natural hormone that regulates iron homeostasis and controls the absorption, storage, and distribution of iron in the body. Rusfertide is currently being evaluated for disorders associated with iron overload and excessive erythrocytosis (red blood cell production).

- In March 2021, following an end-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA") and written comments from the European Medicines Agency ("EMA"), Protagonist has advanced its preparations for a global pivotal study of rusfertide in polycythemia vera ("PV"). The Company plans to initiate this Phase 3 study in early 2022.
- In April 2021, Protagonist announced completion of enrollment in the ongoing Phase 2 study of rusfertide in PV. The Company plans to present updated interim data from this study at an upcoming medical meeting in the second quarter of 2021.
- In the second half of 2021, Protagonist expects to announce preliminary results from the ongoing Phase 2 open-label proof-of-concept study of rusfertide in patients with hereditary hemochromatosis ("HH").
- In addition to ongoing studies in PV and HH, the Company expects to select a third indication for rusfertide in 2021.

Inflammatory Bowel Diseases

PN-943
Investigational, orally delivered, gut-restricted alpha-4-beta-7 specific integrin antagonist for inflammatory bowel diseases.

- The 150-patient Phase 2 "IDEAL" study evaluating the safety, tolerability and efficacy of PN-943 in patients with moderate to severe ulcerative colitis is underway, and the study is on track for completion in 2022.

Oral IL-23 Receptor Antagonists

PTG-200; PN-235; PN-232 (Janssen collaboration)
Investigational, orally delivered, IL-23 receptor antagonists. Protagonist has entered into a worldwide agreement with Janssen to co-develop and commercialize these drug candidates.

- In the second quarter of 2021, Protagonist expects to dose the first subject in the Phase 1 study of PN-232. The Company expects to complete both this trial and the Phase 1 trial of PN-235 in the second half of 2021. PN-232 and PN-235 are part of the oral IL-23 pathway blocker portfolio strategy, pursued in collaboration with Janssen.
- Enrollment continues for the Phase 2a proof-of-concept PRISM study of PTG-200, a first-generation drug candidate for patients with moderate to severe Crohn's disease.

First Quarter 2021 Financial Results

- **Cash, Cash Equivalents and Marketable Securities:** Cash, cash equivalents and marketable securities as of March 31, 2021 were $279.7 million. The Company expects current cash, cash equivalents and marketable securities to be sufficient to fund its planned operating and capital expenditures through the first half of 2024.
- **License and Collaboration Revenue:** License and collaboration revenue was $6.2 million for the first quarter of 2021 compared to $3.6 million for the same period of 2020. The increase was primarily due to the additional services provided to Janssen under the collaboration agreement during 2021 related to PN-232 and PN-235.
- **Research and Development ("R&D") Expenses:** R&D expenses for the first quarter 2021 were $24.2 million as compared to $18.8 million for the same period of 2020. The increase was primarily due to costs associated with advancing our clinical trials with our pipeline assets of rusfertide and PN-943, as well as our three IL-23 receptor antagonist assets under the Janssen collaboration (PTG-200, PN-235 and PN-232).
- **General and Administrative ("G&A") Expenses:** G&A expenses for the first quarter 2021 were $6.0 million as compared to $4.6 million for the same periods of 2020. The increase was primarily related to professional fees and employee compensation related expenses supporting the growth in our operations.
- **Net Loss:** The first quarter net loss was $24.0 million, or a net loss of $0.54 per share, compared to the first quarter of 2020 net loss of $20.1 million, or a net loss of $0.72 per share.

About Protagonist Therapeutics

Protagonist Therapeutics is a clinical stage biopharmaceutical company with multiple peptide-based investigational new chemical entities in different stages of development. Rusfertide (PTG-300) is an investigational, injectable hepcidin mimetic in a Phase 2 proof-of-concept clinical trial for polycythemia vera, and a separate Phase 2 clinical study for hereditary hemochromatosis. Based on the feedback provided by the FDA and EU regulatory authorities, the Company plans to initiate a single, global, Phase 3 randomized, placebo-controlled trial evaluating the efficacy of a once weekly, subcutaneously self-administered dose of rusfertide.

PN-943 is an investigational orally delivered, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide in a 150 patient Phase 2 study for the potential treatment of inflammatory bowel disease, with ulcerative colitis as the initial targeted indication. PTG-200 is an orally delivered, gut-restricted, interleukin-23 receptor specific antagonist peptide in a Phase 2 clinical trial for Crohn's disease. Two additional second-generation oral interleukin-23 receptor antagonist candidates, PN-235 and PN-232, are in early stages of clinical development. The Company has developed a proprietary technology platform to discover and develop novel peptide-based therapeutics to address significant unmet medical needs and transform existing treatment paradigms. 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, our plans to conduct a Phase 3 trial evaluating rusfertide for PV, the timing of initiation and completion of other clinical trials and the timing of clinical data announcements. 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, the impact of the ongoing COVID-19 pandemic on our discovery and development efforts, 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, 2021, 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.
Condensed Consolidated Statements of Operations
(Unaudited)
(Amounts in thousands except share and per share data)

Three Months Ended

	March 31,	
	2021	2020
License and collaboration revenue - related party	$ 6,189	$ 3,647
Operating expenses:		
Research and development [1]	24,245	18,768
General and administrative [1]	5,965	4,576
Total operating expenses	30,210	23,344
Loss from operations	(24,021)	(19,697)
Interest income	102	526
Interest expense	—	(243)
Other expense, net	(79)	(490)
Loss before income tax expense	(23,998)	(19,904)
Income tax expense	—	(176)
Net loss	$ (23,998)	$ (20,080)
Net loss per share, basic and diluted	$ (0.54)	$ (0.72)
Weighted-average shares used to compute net loss per share, basic and diluted	44,224,169	27,703,918

[1] Amounts include non-cash stock-based compensation expense.

Stock-based Compensation
(In thousands)

	Three Months Ended March 31,	
	2021	2020
Research and development	$ 1,475	$ 1,066
General and administrative	1,185	982
Total stock-based compensation expense	$ 2,660	$ 2,048

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

	March 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 279,730	$ 307,809
Working Capital	250,993	275,365
Total assets	298,072	324,468
Deferred revenue-related party	5,768	14,477
Accumulated deficit	(307,809)	(283,811)
Total stockholders' equity	259,334	279,606

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