



Protagonist Reports Second Quarter 2022 Financial Results and Provides Corporate Update

8/4/2022

Continued focus on Phase 3 VERIFY study of rusfertide in polycythemia vera (PV)

Presented new, positive data from Phase 2 REVIVE study of rusfertide in PV at the 2022 ASCO Annual Meeting and the EHA2022 Congress

Strong cash position, with cash runway through end of 2024

NEWARK, Calif., Aug. 4, 2022 /PRNewswire/ -- Protagonist Therapeutics (Nasdaq: PTGX) ("Protagonist" or "the Company") today reported financial results for the second quarter ended June 30, 2022 and provided a corporate update.

"We continue to prioritize the development of rusfertide in polycythemia vera, driving the Phase 3 VERIFY study forward with a focus on data readout with the cash we have on hand," said Dinesh V. Patel, Ph.D., President and Chief Executive Officer of Protagonist. "Updated Phase 2 drug suspension and re-dosing data, recently presented at the 2022 ASCO and EHA conferences, reaffirm rusfertide's potential to improve patients' lives and transform the treatment landscape for PV."

Dr. Patel continued, "Our diverse programs, including both partnered and fully owned assets, provide us with several opportunities to bring new medicines forward to patients and create shareholder value. Our partner, Janssen, is pursuing multiple clinical studies of PN-235, including two Phase 2 studies in moderate-to-severe plaque psoriasis. In parallel with partnership exploration for PN-943, we are engaging with regulators for guidance on the next phase of clinical development. Our cash position remains strong, with runway through the end of 2024. Protagonist's proprietary peptide technology platform confers fundamental strengths that will serve us well in the current environment and over the long term."

Second Quarter 2022 Recent Developments

Rusfertide: Subcutaneous Injectable Heparin Mimetic for Polycythemia Vera (PV) and Other Blood Disorders

- It is the Company's objective to complete the planned 250-patient enrollment in the Phase 3 VERIFY study by the end of the first half of 2023. Notwithstanding a slower than anticipated pace of initial enrollment, 35 study sites have been activated globally to date. The Company continues to implement measures to increase patient recruitment, screening, and enrollment.
- The Company completed patient enrollment in the ongoing Phase 2 REVIVE study of rusfertide in PV in the first quarter of 2022, with a target of approximately 50 patients to be enrolled through the end of the randomized withdrawal portion of the study.
- Highlights of the Phase 2 REVIVE study were shared as an oral presentation by Ronald Hoffman, M.D. at the Annual Meeting of the American Society of Clinical Oncology (ASCO) in Q2 2022. Dr. Hoffman is principal investigator of the Phase 2 REVIVE study, and the Albert A. and Vera G. List Professor of Medicine and Director of the Myeloproliferative Disorders Research Program at the Icahn School of Medicine at Mount Sinai.
- Updated data from the Phase 2 REVIVE study were shared as a poster presentation at the European Hematology Association 2022 Congress (EHA2022), given by Dr. Andrew Kuykendall, M.D., Assistant Member at the Moffitt Cancer Center in the Department of Malignant Hematology.
- Data from the Phase 2 REVIVE study data were presented at the European Iron Club Conference by Dr. Yelena Ginzburg, M.D., Associate Professor of Hematology and Medical Oncology at the Icahn School of Medicine at Mount Sinai.
- Chronic arthropathy occurs in a significant subset of patients with hereditary hemochromatosis (HH). HH arthropathy correlates with iron overload and is associated with transferrin saturation (TSAT), ferritin, elevated age, and unresponsiveness to phlebotomy treatment. Protagonist intends to design a Phase 2 study of rusfertide in this HH sub-population, in consultation with regulatory agencies.

PN-235: Oral IL-23 Receptor Antagonist

- Four clinical studies of PN-235 (JNJ-77242113), a drug candidate discovered by Protagonist and further developed in collaboration with Janssen, are in different stages of clinical development at Janssen. These include
 - FRONTIER 1, a Phase 2b multicenter, randomized, placebo controlled, 240-patient dose-ranging study commenced in early 2022 to evaluate the safety and efficacy of PN-235 for the treatment of moderate-to-severe plaque psoriasis;
 - FRONTIER 2, a long-term extension study;
 - SUMMIT, a study of an oral tablet formulation of PN-235 for the treatment of moderate-to-severe

plaque psoriasis; and

- a separate Phase 1 study of PN-235 in healthy Japanese and Chinese participants. More information on these studies can be found at <https://www.clinicaltrials.gov/>.
- Protagonist is eligible for a \$10 million milestone payment in connection with the start of a second indication-based Phase 2 study. The Company is also eligible for a \$50 million milestone upon dosing of a third patient in a Phase 3 study of PN-235.

PN-943: Oral, Gut-restricted, alpha-4-beta-7 Integrin Antagonist for Ulcerative Colitis (UC)

- The Company submitted a request to FDA for a clinical protocol guidance meeting and is awaiting written responses from FDA related to the Phase 3 study plan. The Phase 3 study plan is anchored around the 150 mg BID dose of PN-943, pending regulatory guidance.
- Protagonist intends to pursue further clinical development of PN-943 in collaboration with a large pharmaceutical partner. As announced previously, the Company has engaged PJT Partners to identify and evaluate such partnering opportunities.
- The results of the IDEAL study have been selected for an oral presentation at the United European Gastroenterology Week (UEGW) in October 2022.
 - Presentation Title: "A Phase 2 Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of the Oral, Gut-Restricted $\alpha 4 \beta 7$ Integrin Peptide Antagonist PN-943 in Patients with Moderate to Severe Ulcerative Colitis: Results from the IDEAL Study."
 - Presentation Date and Time: October 10, 2022; 9:30 AM to 10:30 AM PT
 - Abstract Number: AS-UEG-2022-03120.

Second Quarter 2022 Financial Results

- **Cash, Cash Equivalents and Marketable Securities:** Cash, cash equivalents and marketable securities as of June 30, 2022 were \$291.9 million. The Company expects current cash, cash equivalents and marketable securities to be sufficient to fund its planned operating and capital expenditures through the end of 2024.
- **License and Collaboration Revenue:** License and collaboration revenue was \$0.9 million and \$26.6 million for the three and six months ended June 30, 2022, respectively, as compared to \$2.3 million and \$8.5 million, respectively, for the same periods in 2021. The decrease in revenue from prior year quarter was primarily due to a decrease in the level of services the Company provided under the Janssen license and collaboration agreement. The Company completed a performance obligation pursuant to the collaboration as of June 30, 2022. The revenue increase from prior year-to-date was primarily due to the \$25.0 million milestone that the Company became eligible to receive in March 2022 upon the dosing of the third patient in the Janssen phase 2b Frontier 1 study of PN-235.
- **Research and Development ("R&D") Expenses:** R&D expenses were \$34.6 million and \$70.9 million for the

three and six months ended June 30, 2022 as compared to \$26.4 million and \$50.7 million for the same periods in 2021. The increases were primarily due to costs associated with advancing rusfertide and PN-943, including current and planned Phase 3 clinical trials.

- **General and Administrative ("G&A") Expenses:** G&A expenses were \$7.7 million and \$18.2 million for the three and six months ended June 30, 2022 as compared to \$6.7 million and \$12.7 million for the same periods in 2021. The increases were primarily due to personnel expenses and other expenses to support Company growth.
- **Net Loss:** Net loss was \$41.0 million, or \$0.84 per share, for the three months ended June 30, 2022 as compared to a net loss of \$30.8 million, or \$0.69 per share, for the three months ended June 30, 2021. Net loss was \$62.0 million, or \$1.27 per share, for the six months ended June 30, 2022 as compared to a net loss of \$54.8 million, or \$1.23 per share for the six months ended June 30, 2021.

About Protagonist

Protagonist Therapeutics is a biopharmaceutical company with peptide-based new chemical entities rusfertide, PN-943, and PN-235 in different stages of clinical development, all derived from the Company's proprietary technology platform. Rusfertide, a mimetic of the natural hormone hepcidin, is the Company's lead drug candidate. VERIFY, the global Phase 3 registrational study of rusfertide in polycythemia vera, is currently underway. Protagonist is headquartered in Newark, California. For more information on Protagonist, please visit the Company's website at 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 secure a collaborative partner to support further clinical development of PN-943, the clinical development of rusfertide and our expectations regarding clinical trial enrollment, our expected cash runway and potential milestones related to PN-235. 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 agreements, the impact of the current COVID-19 pandemic on our discovery and development efforts, the impact of the ongoing military conflict in Ukraine and Russia on any future studies, 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 most recently filed periodic reports on Form 10-K and Form 10-Q 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
(Amounts in thousands except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
License and collaboration revenue - related party	\$ 859	\$ 2,265	\$ 26,581	\$ 8,454
Operating expenses:				
Research and development (1)	34,611	26,432	70,929	50,677
General and administrative (1)	7,691	6,715	18,206	12,680
Total operating expenses	42,302	33,147	89,135	63,357
Loss from operations	(41,443)	(30,882)	(62,554)	(54,903)
Interest income	484	97	652	199
Other expense, net	(78)	(57)	(65)	(136)
Net loss	<u>\$ (41,037)</u>	<u>\$ (30,842)</u>	<u>\$ (61,967)</u>	<u>\$ (54,840)</u>
Net loss per share, basic and diluted	<u>\$ (0.84)</u>	<u>\$ (0.69)</u>	<u>\$ (1.27)</u>	<u>\$ (1.23)</u>
Weighted-average shares used to compute net loss per share, basic and diluted	<u>49,049,902</u>	<u>44,964,637</u>	<u>48,902,047</u>	<u>44,546,172</u>

(1) Amount includes non-cash stock-based compensation expense

PROTAGONIST THERAPEUTICS, INC.
Stock-based Compensation
(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development	\$ 4,106	\$ 2,155	\$ 7,432	\$ 3,630
General and administrative	2,699	1,781	5,308	2,966
Total stock-based compensation expense	\$ 6,805	\$ 3,936	\$ 12,740	\$ 6,596

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

	June 30, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	\$ 291,890	\$ 326,900
Working capital	264,214	269,720
Total assets	310,512	347,695
Deferred revenue-related party	-	1,601
Accumulated deficit	(471,329)	(409,362)
Total stockholders' equity	267,978	300,021

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