Protagonist Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Corporate Update

2/28/2022

Pivotal Phase 3 VERIFY study of rusfertide in polycythemia vera expected to initiate in Q1 2022
Topline results from the Phase 2 IDEAL study of PN-943 in ulcerative colitis expected in Q2 2022
Dosing has begun in a 240-patient Phase 2b clinical trial of PN-235 in moderate-to-severe plaque psoriasis, sponsored by Janssen
NEWARK, Calif., Feb. 28, 2022 /PRNewswire/ -- Protagonist Therapeutics (Nasdaq: PTGX) ("Protagonist" or "the Company") today reported financial results for the fourth quarter and full year ended December 31, 2021 and provided a corporate update.

"This past quarter and the year leading up to it has been a transformational period for Protagonist," said Dinesh V. Patel, Ph.D., President and Chief Executive Officer of Protagonist. "Today, we are closer than ever to fulfilling the potential of three diverse strategies reflected in our robust pipeline: (1) moving rusfertide into a Phase 3 registrational study for a rare disease indication like polycythemia vera, (2) completing enrollment for PN-943 Phase 2 proof-of-concept study in a common and prevalent disease like ulcerative colitis, and (3) enabling our partner, Janssen, to progress PN-235 into a Phase 2b study in plaque psoriasis and potentially other indications in inflammatory bowel diseases in the later part of the year. Each of these three assets and their potential to treat diverse diseases represent a multi-billion-dollar opportunity for Protagonist."

Dr. Patel continued: "In the last quarter and year, we have demonstrated exceptional strength of execution in progressing our assets further in clinical development. For rusfertide in PV, we announced updated Phase 2 data at EHA and ASH, and recently unveiled the design of our Phase 3 VERIFY study, which is set to initiate this quarter. With great anticipation, we look forward to the topline data readout from the Phase 2 IDEAL study of PN-943 in ulcerative colitis in the second quarter of this year. We're very pleased that the 240-patient Phase 2b study of PN-

235 in plaque psoriasis has initiated, with the first patient dosed recently. Looking ahead, we plan to continue to demonstrate our strength of execution across all current and emerging assets in our pipeline, thereby maximizing the opportunities ahead of us for substantial value creation this year."

Fourth Quarter 2021 Recent Developments and Upcoming Milestones

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

- Most recent data from the ongoing Phase 2 REVIVE study of rusfertide in PV were presented at the American Society of Hematology (ASH) December 2021 Annual Meeting. Findings from the open label portion of this study continued to demonstrate rusfertide's ability to markedly reduce the need for therapeutic phlebotomies (TP) in a majority of PV patients, along with additional observed effects including rapid, sustained, and durable hematocrit (HCT) control.
- Also at ASH 2021, the Company presented results from the PACIFIC Phase 2 study of rusfertide for PV patients with high HCT levels. Data demonstrated that post-induction, weekly rusfertide treatment rapidly controlled HCT levels without the need for TP.
- Protagonist is preparing to initiate the VERIFY study, a pivotal Phase 3 clinical trial of rusfertide for 250 patients living with PV, in Q1 2022. The design of the upcoming clinical trial was also presented at ASH in December 2021.
- Data from an open-label Phase 2 clinical trial of rusfertide in HH were presented at The Liver Meeting in November 2021, hosted by the American Association for the Study of Liver Diseases. This data demonstrated rusfertide's ability to reduce phlebotomy rates and other biomarkers associated with the disease in the study population. The Company plans to identify potential target sub-populations and next steps in 1H 2022 to advance the program.

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

- PN-943 is currently being evaluated in moderate-to-severe UC in the Company's Phase 2 IDEAL study. The clinical trial has completed its target enrollment of 150 patients, and the Company plans to share topline results from the study, including data from the 12-week induction period, in Q2 2022.

PN-235: Oral IL-23 Receptor Antagonist

- A Phase 2b study of PN-235 (JNJ-77242113) in participants with moderate-to-severe plaque psoriasis (FRONTIER 1) initiated in early 2022, sponsored by Janssen Biotech (Janssen). PN-235 is a second-generation oral peptide IL-23 receptor antagonist being developed under the worldwide license and collaboration agreement with Janssen. PN-235 is also expected to advance into Phase 2 clinical studies in inflammatory bowel diseases in 2H 2022. The Company will earn a $25 million milestone in connection with the dosing of a

third patient in FRONTIER 1. Protagonist is also eligible for a $10 million milestone in connection with the start of the second indication-based Phase 2 study.

Fourth Quarter 2021 Financial Results

- Cash, Cash Equivalents and Marketable Securities: Cash, cash equivalents and marketable securities as of December 31, 2021 were $326.9 million. The Company expects current cash, cash equivalents and marketable securities to be sufficient to fund its planned operating and capital expenditures through 2024. Our cash forecast will be updated following the PN-943 Phase 2 study UC data readout in the second quarter of 2022.
- License and Collaboration Revenue: License and collaboration revenue was $8.6 million for the fourth quarter of 2021 compared to $5.7 million for the same period of 2020. The increase was primarily due to an increase in services provided to Janssen under the collaboration agreement during 2021 related to PN-232 and PN-235 as the company nears completion of the services to be performed. License and collaboration revenue for the full year 2021 was $27.4 million compared to $28.6 million for 2020. The full year 2021 collaboration revenue included a cumulative catch-up amount of $8.0 million following the July 2021 amendment of its collaboration agreement for the development of IL23-R assets with Janssen. Revenue for the prior year 2020 included an update to the forecast for remaining services to be completed under the collaboration, which accelerated our overall percentage completion under the accounting performance obligation and accelerated revenue recognition.
- Research and Development ("R&D") Expenses: R&D expenses for the fourth quarter and full year 2021 were $38.4 million and $126.0 million respectively, as compared to $19.5 million and $74.5 million, respectively, for the same periods of 2020. The increases in 2021 were primarily due to the additional costs associated with advancing rusfertide and PN-943 through Phase 2 studies and our preparations for future Phase 3 clinical study initiations, as well as expenses related to our Phase 1 studies for our second-generation IL23-R antagonist assets under the Janssen collaboration. R&D expenses also increased due to higher research spending and employee related costs, including stock-based compensation expenses following recent hiring in support of our advancing research and development programs.
- General and Administrative ("G&A") Expenses: G&A expenses for the fourth quarter and full year 2021 were $7.3 million and $27.2 million, respectively, as compared to $5.0 million and $18.6 million for the same periods of 2020. The increases were primarily related to professional fees, insurance costs and employee compensation related expenses, including stock-based compensation expenses, supporting the growth in our operations.
- Stock-based Compensation ("SBC") Expenses: SBC expenses for the fourth quarter and full year ended December 31, 2021 were $5.0 million and $16.4 million, respectively, as compared to $2.0 million and $7.9 million, respectively, for the same periods of 2020. The increases in 2021 (included in R&D and G&A expenses above) were primarily attributable to awards granted to new employees hired to support the Company's continued growth and an increase in the Company's stock price at the grant dates during 2021.

- Net Loss: The fourth quarter 2021 net loss was $36.9 million, or a net loss of $0.77 per share, and for the year ended December 31, 2021, net loss was $125.6 million, or a net loss of $2.71 per share, compared to the fourth quarter of 2020 net loss of $18.9 million, or a net loss of $0.48 per share, and for the year ended December 31, 2020, net loss of $66.2 million, or a net loss of $1.92 per share.

About Protagonist

Protagonist Therapeutics is a biopharmaceutical company with multiple peptide-based new chemical entities in different stages of clinical development, all derived from the Company's proprietary technology platform.

Protagonist's pipeline includes rusfertide, an investigational, injectable hepcidin mimetic currently in the REVIVE Phase 2 proof-of-concept clinical trial for polycythemia vera (PV), the PACIFIC Phase 2 study in PV subjects with high hematocrit levels, and a recently completed Phase 2a study for hereditary hemochromatosis. The Company is actively initiating VERIFY, a single, global Phase 3 randomized, placebo-controlled trial evaluating the efficacy and safety of a once weekly, subcutaneously self-administered dose of rusfertide.

The Company is also evaluating an orally delivered, gut-restricted alpha-4-beta-7 integrin specific antagonist peptide (PN-943), currently in the IDEAL Phase 2 study in adults with moderate to severe active ulcerative colitis. The Company is targeting ulcerative colitis as the initial indication.

The Company has a worldwide license and collaboration agreement with Janssen Biotech, Inc., for the development of oral peptide interleukin-23 receptor (IL23-R) antagonist PN-235 (JNJ-77242113). Under the collaboration, Janssen is advancing PN-235 into FRONTIER 1, a Phase 2b study in plaque psoriasis and is expected to advance at least one new Phase 2 clinical study in inflammatory bowel disease.

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 Company's clinical development programs for rusfertide and PN-943, the potential benefits of rusfertide in PV patients and the clinical development of 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, 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 December 31,		Year Ended December 31,	
	2021	2020	2021	2020
License and collaboration revenue - related party	$ 8,617	$ 5,650	$ 27,357	$ 28,628
Operating expenses:				
Research and development (1)	38,373	19,486	126,006	74,506
General and administrative (1)	7,260	4,994	27,196	18,638
Total operating expenses	45,633	24,480	153,202	93,144
Loss from operations	(37,016)	(18,830)	(125,845)	(64,516)
Interest income	122	80	443	900
Interest expense	—	(127)	—	(598)
Loss on early repayment of debt	—	—	—	(585)
Other expense, net	(13)	(9)	(149)	(46)

Loss before income tax expense	(36,907)	(18,886)	(125,551)	(64,845)
Income tax expense	—	—	—	(1,305)
Net loss	$ (36,907)	$ (18,886)	$ (125,551)	$ (66,150)
Net loss per share, basic and diluted	$ (0.77)	$ (0.48)	$ (2.71)	$ (1.92)
Weighted-average shares used to compute net loss per share, basic and diluted	48,154,171	39,605,193	46,322,910	34,396,446

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

PROTAGONIST THERAPEUTICS, INC.

Stock-based Compensation

(In thousands)

	Three Months Ended December 31,		Year Ended December 31,	
	2021	2020	2021	2020
Research and development	$ 2,755	$ 1,023	$ 8,996	$ 4,121
General and administrative	2,269	944	7,399	3,778
Total stock-based compensation expense	$ 5,024	$ 1,967	$ 16,395	$ 7,899

PROTAGONIST THERAPEUTICS, INC.

Selected Consolidated Balance Sheet Data

(In thousands)

	December 31, 2021	December 31, 2020
Cash, cash equivalents and marketable securities	$ 326,900	$ 307,809
Working capital	296,720	275,365
Total assets	347,695	324,468
Deferred revenue-related party	1,601	14,477
Accumulated deficit	(409,362)	(283,811)
Total stockholders' equity	300,021	279,606

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