Prometheus Biosciences Reports Third Quarter 2022 Financial Results and Highlights Recent Corporate Progress

November 9, 2022

- On track for topline ARTEMIS-UC Phase 2 and full APOLLO-CD Phase 2a results concurrently in 4Q 2022 -

- Initiation of Phase 1 trial of second precision program PRA052 -

- Strong cash position provides runway into mid-2024 -

SAN DIEGO, Nov. 09, 2022 (GLOBE NEWSWIRE) -- Prometheus Biosciences, Inc. (Nasdaq: RXDX), a clinical-stage biotechnology company pioneering a precision medicine approach for the discovery, development, and commercialization of novel therapeutic and companion diagnostic products for the treatment of immune-mediated diseases, today reported financial results for the quarter ended September 30, 2022 and highlighted recent corporate progress.

“During the third quarter, we demonstrated substantial progress by advancing both clinical assets, PRA023 and PRA052, and we are encouraged by the solid momentum leading us into year-end,” said Mark McKenna, Chairman and CEO. “We are eager to readout the topline results in ARTEMIS-UC and full results in APOLLO-CD Phase 2 studies concurrently.”

Third Quarter 2022 and Recent Corporate Highlights

PIPELINE AND PLATFORM HIGHLIGHTS

On track for topline ARTEMIS-UC Phase 2 study results in 4Q. Prometheus completed enrollment in the initial cohort (Cohort 1) of the Phase 2 study of PRA023 for ARTEMIS-UC in ulcerative colitis in July. The expansion cohort (Cohort 2), which is designed to further evaluate the effectiveness of Prometheus’ companion diagnostic, began enrollment in July. The Company plans to report topline results from the initial cohort and an update on the expansion cohort in the fourth quarter.

On track for full APOLLO-CD global Phase 2a study results in 4Q. During the second quarter of 2022, Prometheus completed enrollment for APOLLO-CD, a global Phase 2a study of PRA023 in Crohn’s Disease (CD). The Company plans to report full results from this study in the fourth quarter.

Bioavailability greater than 80% achieved upon completion of PRA023 subcutaneous dosing in NHV. Prometheus completed its subcutaneous bridging study in Caucasian normal healthy volunteers that demonstrated bioavailability of greater than 80%. This favorable bioavailability combined with a subcutaneous formulation of 200 mg/ml provides significant differentiation and flexibility with respect to dosing regimen in future registration studies and beyond. The Company plans to implement an autoinjector in potential future UC and CD registrational studies.

PRA052 IND cleared by the FDA and Phase 1 study has been initiated. Prometheus received IND clearance from the FDA and initiated a Phase 1 trial in normal healthy volunteers for its second precision candidate, PRA052, a potential first-in-class monoclonal antibody blocking CD30 ligand. CD30L is a costimulatory molecule that has been implicated in inflammatory bowel disease (IBD) by genetic, preclinical, and human translational data. Prometheus is also developing a companion diagnostic candidate designed to select potential responders for this program.

THIRD QUARTER 2022 FINANCIAL RESULTS

Cash, Cash Equivalents and Short-Term Investments. As of September 30, 2022, Prometheus had cash, cash equivalents and short-term investments of $260.2 million, compared to $257.3 million at the end of Q4 2021. Subsequent to September 30, 2022, the Company raised an additional $1.1 million in net proceeds under its ATM facility. Prometheus believes its cash, cash equivalents and short-term investments, including these additional ATM proceeds, will be sufficient to fund its operating expenses and capital expenditure requirements into mid-2024.

Research and Development (R&D) Expenses. Research and development expenses were $29.1 million for the three months ended September 30, 2022 compared to $17.6 million for the three months ended September 30, 2021 primarily due to advancement of PRA023 in global Phase 2 clinical trials and PRA052 toward IND.

About PRA023: Pipeline in a Product Candidate

PRA023 is an IgG1 humanized monoclonal antibody that has been shown to block tumor necrosis factor (TNF)-like ligand 1A (TL1A). PRA023 binds both soluble and membrane-associated human TL1A with high affinity and specificity and has the potential to substantially improve outcomes for moderate-to-severe IBD patients predisposed to increased TL1A expression. Prometheus is developing PRA023 for the treatment of immune-mediated diseases including UC, CD, and systemic sclerosis-associated interstitial lung disease (SSc-ILD).

The Company is currently conducting three Phase 2 studies of PRA023: a Phase 2 trial in UC patients, ARTEMIS-UC, a Phase 2a trial in CD patients, APOLLO-CD, and a Phase 2 trial in SSc-ILD, ATHENA-SSc-ILD, each utilizing a genetic-based companion diagnostic candidate designed to identify patients who are predisposed to increased expression of TL1A and therefore potentially more likely to respond to PRA023.

About Prometheus Biosciences

Prometheus Biosciences, Inc. is a clinical-stage biotechnology company pioneering a precision medicine approach for the discovery, development, and commercialization of novel therapeutic and companion diagnostic products for the treatment of immune-mediated diseases. The company's precision medicine platform, Prometheus360™, combines proprietary machine learning-based analytical approaches with one of the world's largest gastrointestinal bioinformatics databases to identify novel therapeutic targets and develop therapeutic candidates to engage those targets.

Forward Looking Statements

Prometheus cautions readers that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to statements regarding: the timing of Prometheus obtaining and reporting the topline study results from its Phase 2 clinical trial of PRA023 in UC and the final study results from its Phase 2a clinical trial of PRA023 in CD; the timing of completing Prometheus' Phase 1 clinical trial of PRA052 and reporting results; the potential of Prometheus' companion diagnostic candidates to identify responders; Prometheus' use of such companion diagnostic candidates in planned and other future clinical trials; Prometheus' Enroll360 program and the Company's ability to accelerate enrollment in its planned and other future clinical trials; Prometheus' ability to potentially implement an autoinjector in future registrational studies; and the sufficiency of the Company's current cash position to fund operations through mid-2024. The inclusion of forward-looking statements should not be regarded as a representation by Prometheus that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: Prometheus' approach to the discovery and development of precision medicines based on Prometheus360 is unproven; potential delays in the commencement, enrollment and completion of clinical trials and preclinical studies; the results of preclinical studies and early clinical trials are not necessarily predictive of future results; Prometheus' dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; Prometheus' ability to develop companion diagnostics for its therapeutic product candidates; unexpected adverse side effects or inadequate efficacy of its product candidates that may limit their development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; regulatory developments in the United States and foreign countries; Prometheus' ability to maintain undisrupted business operations due to the COVID-19 pandemic, including delaying or otherwise disrupting its preclinical studies, clinical trials, manufacturing and supply chain; Prometheus could use its available capital resources sooner than it currently expects; and other risks described in the Company's prior press releases and filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in Prometheus' most recent quarterly report on Form 10-Q and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Prometheus undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

Prometheus Biosciences, Inc.
Condensed Balance Sheets
(unaudited)
(in thousands)

	September 30, 2022	December 31, 2021
Assets		
Cash and cash equivalents	$ 78,413	$ 257,254
Short term investments	181,835	—
Other current assets	5,808	8,129
Total current assets	266,056	265,383
Other non-current assets	32,562	2,418
Total assets	$ 298,618	$ 267,801
Liabilities and Stockholders' Equity		
Current liabilities	$ 23,779	$ 16,442
Long-term liabilities	42,304	16,204
Total liabilities	66,083	32,646
Total stockholders' equity	232,535	235,155
Total liabilities and stockholders' equity	$ 298,618	$ 267,801

Prometheus Biosciences, Inc.
Condensed Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration revenue	$ 968	$ 1,006	$ 6,156	$ 2,092
Operating expenses:				
Research and development	29,079	17,551	82,906	38,863

General and administrative	10,272	10,248	27,698	21,088
Total operating expenses	39,351	27,799	110,604	59,951
Loss from operations	(38,383)	(26,793)	(104,448)	(57,859)
Other income (expense), net	1,108	(540)	1,460	(2,418)
Net loss	$ (37,275)	$ (27,333)	$ (102,988)	$ (60,277)
Other comprehensive loss:				
Unrealized loss on marketable securities, net	(141)	-	(451)	-
Comprehensive loss	$ (37,416)	$ (27,333)	$ (103,439)	$ (60,277)
Net loss per share, basic and diluted	$ (0.90)	$ (0.70)	$ (2.59)	$ (2.09)
Weighted average shares outstanding - basic and diluted	41,218,645	38,848,412	39,831,114	28,778,814

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