UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): November 12, 2021

PROMETHEUS BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-40187**	**81-4282653**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

9410 Carroll Park Drive
San Diego, California 92121
(Address of principal executive offices) (Zip Code)

858-824-0895
(Registrant's telephone number, include area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**RXDX**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 12, 2021, Prometheus Biosciences, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2021. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued on November 12, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PROMETHEUS BIOSCIENCES, INC.

Date: November 12, 2021

By: /s/ Timothy K. Andrews
Timothy K. Andrews
General Counsel and Secretary

Exhibit 99.1

Prometheus Biosciences Reports Third Quarter 2021 Financial Results and Highlights Recent Corporate Progress

-Full clinical trial results from Phase 1a trial of PRA023 and announcement of a third Phase 2 indication for PRA023 expected in fourth quarter 2021 -

- Enrollment on track for Phase 2 in ulcerative colitis and Phase 2a in Crohn's disease with topline data from both trials anticipated by fourth quarter 2022 -

- Enrolled over 1,500 patients in the Prometheus Enroll360™ platform to support future studies -

- Strong cash position of $279 million as of September 30, 2021-

San Diego – November 12, 2021 - 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, starting first with inflammatory bowel disease (IBD), today reported financial results for the quarter ended September 30, 2021.

"We advanced significant milestones in the third quarter with the initiations of our two Phase 2 trials in ulcerative colitis and Crohn's disease and are on track to readout the topline data of these two trials in the fourth quarter of 2022," said Mark McKenna, Chairman and CEO of Prometheus. "We look forward to announcing our full Phase 1a trial results and expanding PRA023 into a new indication beyond IBD this quarter."

Third Quarter 2021 and Recent Corporate Highlights

Initiated global Phase 2 ARTEMIS-UC clinical trial of PRA023 in Ulcerative Colitis (UC). Prometheus' Phase 2 ARTEMIS-UC clinical trial is currently enrolling patients with moderate-to-severely active UC who have failed conventional therapy, including biologics. The trial is a 12-week, double-blind, placebo-controlled, randomized study to evaluate the efficacy and safety of PRA023 in patients with UC. The initial cohort is statistically powered to evaluate the efficacy of PRA023 in patients with UC. The expansion cohort is statistically powered to further evaluate the effectiveness of the company's companion diagnostic in patients with UC. Topline results for the Phase 2 ARTEMIS-UC trial are expected in 4Q 2022.

Initiated global Phase 2a APOLLO-CD clinical trial of PRA023 in Crohn's disease (CD). Prometheus' Phase 2a APOLLO-CD clinical trial is a 12-week open label study that is currently enrolling patients with moderate-to-severely active CD with endoscopically active disease who have failed conventional therapy, including biologics. The study will assess the efficacy of PRA023 and the effectiveness of the company's companion diagnostic in patients with CD. Topline results for the Phase 2a APOLLO-CD trial are expected in 4Q 2022.

Enrolled over 1,500 patients in Prometheus Enroll360™ platform. Prometheus' Enroll360™ is a global patient recruitment platform that is designed to accelerate development timelines by improving the efficiency of patient identification and increasing the rate of enrollment for the company's biomarker-guided clinical trials. Prometheus is building a global network of trial-ready sites where over 5,000 patients will be molecularly profiled and clinically characterized to determine their eligibility for Prometheus clinical trials. The company plans to utilize Enroll360™ in Prometheus' companion diagnostic-paired clinical trials for PRA023 as well as future programs.

Prometheus Biosciences and Abveris announce multi-target antibody discovery collaboration. Prometheus and Abveris entered into a multi-year collaboration to develop therapeutic antibodies. The collaboration will support the expansion of Prometheus' portfolio and complement internal antibody development capabilities.

Upcoming Milestones and Events

- Final results from the Phase 1a trial of PRA023 expected in 4Q 2021
- New indication announcement for PRA023 in 4Q 2021
- Investigational Device Exemption (IDE) submission of the companion diagnostic for PRA023 planned for 3Q 2022
- IND submission for PR600 planned for 3Q 2022
- Topline results from the ARTEMIS-UC Phase 2 study expected in 4Q 2022
- Topline results from APOLLO-CD Phase 2a study expected in 4Q 2022

Third Quarter 2021 Financial Results

Cash and Cash Equivalents. As of September 30, 2021, Prometheus Biosciences had cash and cash equivalents of $279.1 million, compared to $54.2 million at the end of 2020. We received net proceeds of $73.7 million from the sale of shares of our Series D-2 convertible preferred stock and net proceeds of $199.8 million from the sale of our common stock in our IPO, both in the first quarter.

Collaboration Revenue. Revenue was $1.0 million for the quarter ended September 30, 2021, compared to $0.4 million for the quarter ended September 30, 2020. Revenues were $2.1 million for the first nine months of 2021 compared to $0.8 million for the first nine months of 2020 primarily due to additional revenue generated from Prometheus' collaboration with Dr. Falk Pharma.

Research and Development Expenses. Research and development expenses were $17.6 million for the quarter ended September 30, 2021, compared to $4.7 million for the quarter ended September 30, 2020, and $38.9 million for the first nine months of 2021 compared to $13.8 million for the first nine months of 2020. The increases were primarily driven by advancement of PRA023 into global Phase 2 clinical trials, as well as advancing our other development programs.

General and Administrative Expenses. General and administrative expenses were $10.2 million for the quarter ended September 30, 2021, compared to $3.2 million for the quarter ended September 30, 2020, and $21.1 million for the first nine months of 2021 compared to $7.4 million for the first nine months of 2020. The increases were primarily due to an increase in expenses related to operating as a public company and an increase in personnel and stock-based compensation.

About PRA023

PRA023 is an IgG1 humanized monoclonal antibody (mAb) 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 the two most common forms of IBD, Ulcerative Colitis (UC) and Crohn's disease (CD). The Company has initiated enrollment in a Phase 2 trial in UC patients and a Phase 2a trial in CD patients, each utilizing a genetic-based companion diagnostic 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, starting first with inflammatory bowel disease (IBD). 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 our current beliefs and expectations. Such forward-looking statements include, but are not limited to statements regarding: the potential to rapidly enroll and execute our clinical trials and expand our approach to other immune-mediated diseases beyond IBD; our Enroll360 program and ability to accelerate enrollment in our planned and other future clinical trials; Prometheus' expected timing of topline results for its Phase 2 and 2a trials, final Phase 1a study results and new indication announcement for PRA023, IDE submission for the PRA023 companion diagnostic, and IND submission for PR600; and the potential for the collaboration with Abveris and internal antibody development programs to support the expansion of our portfolio. The inclusion of forward-looking statements should not be regarded as a representation by Prometheus that any of our 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, and the company may not be able to develop any therapeutics or companion diagnostic products of commercial value; potential delays in the commencement, enrollment and completion of clinical trials and preclinical studies, including due to the COVID-19 pandemic; Prometheus' dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing, and potential supply chain disruptions related to the COVID-19 pandemic; Prometheus' ability to develop a companion diagnostic for PRA023; the success of clinical trials and preclinical studies for its product candidates and companion diagnostic; unexpected adverse side effects or inadequate efficacy of our product candidates that may limit their development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; the results of preclinical studies and early clinical trials are not necessarily predictive of future results; regulatory developments in the United States and foreign countries; Prometheus may not realize any benefits from our collaboration with Dr. Falk or Abveris; and other risks described in our prior press releases and filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our 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 we undertake 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 Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Collaboration revenue	$ 1,006	$ 359	$ 2,092	$ 766
Operating expenses:				
Research and development	17,551	4,652	38,863	13,840
General and administrative	10,248	3,173	21,088	7,370
Total operating expenses	27,799	7,825	59,951	21,210
Loss from operations	(26,793)	(7,466)	(57,859)	(20,444)
Other income (expense), net	(540)	(360)	(2,418)	(1,487)
Loss from continuing operations	(27,333)	(7,826)	(60,277)	(21,931)
Loss from discontinued operations	—	879	—	(6,584)
Net loss	$ (27,333)	$ (6,947)	$ (60,277)	$ (28,515)
Net loss per share, basic and diluted				
Continuing operations	$ (0.70)	$ (5.13)	$ (2.09)	$ (15.21)
Discontinued operations	$ —	$ 0.58	$ —	$ (4.57)
Net loss per share, basic and diluted	$ (0.70)	$ (4.55)	$ (2.09)	$ (19.78)
Weighted average shares outstanding - basic and diluted	38,848,412	1,526,122	28,778,814	1,441,516

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

	September 30, 2021	December 31, 2020
Assets		
Cash and cash equivalents	$ 279,116	$ 54,201
Other current assets	7,992	3,255
Total current assets	287,108	57,456
Other assets	1,830	2,177
Total assets	$ 288,938	$ 59,633
Liabilities and Stockholders' Equity		
Current liabilities	$ 15,093	$ 15,255
Long-term liabilities	11,745	15,896
Total liabilities	26,838	31,151
Convertible preferred stock	—	126,023
Total stockholders' equity (deficit)	262,100	(97,541)
Total liabilities and stockholders' equity (deficit)	$ 288,938	$ 59,633

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