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): October 3, 2022

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.)**

3050 Science Park Road
San Diego, California 92121
(Address of principal executive offices) (Zip Code)

(858) 422-4300
(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 8.01. Other Events.

On October 3 2022, Prometheus Biosciences, Inc. ("Prometheus" or the "Company") announced that the U.S. Food and Drug Administration ("FDA") cleared the Company to proceed with a clinical trial under its investigational new drug application ("IND") for PRA052 in ulcerative colitis. Prometheus expects to initiate a Phase 1 single ascending dose/multiple ascending dose clinical trial in normal healthy volunteers in the fourth quarter of 2022.

Forward Looking Statements

Prometheus cautions readers that statements contained in this report 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 initiating a Phase 1 clinical trial for PRA052 and the anticipated trial design; and the potential for PRA052 to treat ulcerative colitis. 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 report due to the risks and uncertainties inherent in our business, including, without limitation: our approach to the discovery and development of precision medicines based on Prometheus360™ is unproven, and we do not know whether we will 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; we are early in our development efforts and have only one product candidate in early clinical development and all of our other development programs are in the preclinical or discovery stage; the success of clinical trials and preclinical studies for our product candidates; the results of preclinical studies and early clinical trials are not necessarily predictive of future results; our dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; 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; our ability to develop companion diagnostics for our therapeutic product candidates; regulatory developments in the United States and foreign countries, including with respect to INDs and similar foreign regulatory filings and the proposed design of future clinical trials; our ability to maintain undisrupted business operations due to the COVID-19 pandemic or other geopolitical events, including delaying or otherwise disrupting its clinical trials, manufacturing and supply chain; and other risks described in our filings with the SEC, including under the heading "Risk Factors" in our Form 10-K filed with the SEC on March 9, 2022 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 except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. 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.

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: October 3, 2022

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