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): June 6, 2022

PRAXIS PRECISION MEDICINES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39620**	**47-5195942**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Praxis Precision Medicines, Inc.
99 High Street, 30th Floor
Boston, Massachusetts 02110
(Address of principal executive offices, including zip code)

(617) 300-8460
(Registrant's telephone number, including area code)

Not Applicable
(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	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**PRAX**	**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.

PRAX-114 Aria Study Readout

On June 6, 2022, Praxis Precision Medicines, Inc. (the "Company") announced that the Phase 2/3 Aria Study evaluating the efficacy and safety of PRAX-114 for monotherapy treatment of major depressive disorder ("MDD") did not achieve statistical significance on the primary endpoint of change from baseline in the 17-item Hamilton Depression Rating Scale total score at Day 15, or on any secondary endpoints. The Company intends to share detailed results in an upcoming medical presentation or publication.

The Company is closing screening in the Phase 2 Acapella Study evaluating PRAX-114 for treatment of MDD at doses up to 60 mg, and intends to read out results from approximately 100 patients in the third quarter of 2022. The Company is stopping enrollment in its Phase 2 study evaluating PRAX-114 for the treatment of post-traumatic stress disorder, and intends to review the safety data once available. The Company is discontinuing its Phase 2 crossover study to evaluate the safety, pharmacokinetics and efficacy of daytime dosing of PRAX-114 for the treatment of essential tremor ("ET").

The Company is undergoing a strategic realignment to focus resources on its Movement Disorders and Epilepsy franchises, which will result in a reduction of the Company's workforce and future operating expenses. As a result of the realignment, the Company's cash runway will now extend into 2024. The strategic realignment will focus on delivering Phase 2b results for PRAX-944 in ET (Essential1 Study) and proof-of-concept for PRAX-562 in epilepsy and advancing the preclinical pipeline.

PRAX-222 IND Update

On May 25, 2022, the Company received a clinical hold letter from the U.S. Food and Drug Administration (the "FDA") providing additional information on the clinical hold placed on the Company's Investigational New Drug application (the "IND") for the study of PRAX-222, an antisense oligonucleotide for the treatment of patients with SCN2A gain-of-function mutations. On May 31, 2022, the Company submitted a request for clarification to which the FDA responded on June 1, 2022. These communications indicated that, upon submission of additional documentation in relation to the completed 13-week non-human primate toxicology study supporting the starting dose proposed by the Company, the IND could be cleared. The Company intends to request a Type A meeting to confirm the study design and clarify the requirements for dose escalation beyond the starting dose.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the development of the Company's product candidates, the strategic realignment, the Company's cash runway and the clinical hold of the PRAX-222 study. The express or implied forward-looking statements included in this Form 8-K are only predictions and are subject to a number of risks, uncertainties and assumptions, including, without limitation: uncertainties inherent in clinical trials; the expected timing of review by governmental authorities; and other risks concerning the Company's programs and operations described in additional detail in its Annual Report on Form 10-K for the year ended December 31, 2021, its Quarterly Reports on Form 10-Q and other filings made with the Securities and Exchange Commission from time to time. These statements are based only on facts currently known by the Company and speak only as of the date of this Current Report on Form 8-K. As a result, you are cautioned not to rely on these forward-looking statements and the Company undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

SIGNATURE

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.

PRAXIS PRECISION MEDICINES, INC.

Date: June 6, 2022

By: /s/ Marcio Souza

Marcio Souza

Chief Executive Officer