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): September 2, 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-562 Phase 2 Clinical Study

On September 2, 2022, Praxis Precision Medicines, Inc. (the "Company") received an email communication from the U.S. Food and Drug Administration (the "FDA") that the Company's Investigational New Drug ("IND") application for PRAX-562, a first-in-class small molecule in development for the treatment of developmental and epileptic encephalopathies ("DEE") as a preferential inhibitor of persistent sodium current, was placed on clinical hold. PRAX-562 has been dosed in over 130 healthy volunteers in completed and ongoing studies, including 66 in the United States under an initial IND for adult rare headache conditions. Following the clearance of such initial IND, the Company completed the chronic and juvenile toxicology programs and submitted a second IND to the FDA. The Company has initiated discussions with the FDA to provide clarification about the pre-clinical and clinical data packages in relation to the clinical hold correspondence. The Company intends to start the Phase 2 study in pediatric SCN2A and SCN8A DEE patients outside of the United States before the end of 2022, and expects topline results in 2023.

PRAX-222 EMBRAVE Clinical Study

On September 7, 2022, the Company announced its plan to start the PRAX-222 EMBRAVE clinical study for the treatment of pediatric patients with early-seizure-onset SCN2A DEE, after the FDA cleared the Company's IND application for the initial dose cohort. Following collection of the safety and efficacy data from the first cohort of patients in the EMBRAVE study, the data will be evaluated and submitted to the FDA to seek authorization for further dose escalation.

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 timing of the PRAX-562 Phase 2 clinical study and the PRAX-222 EMBRAVE clinical study. The forward-looking statements included in this Current Report on Form 8-K are subject to a number of risks, uncertainties and assumptions, including, without limitation, the expected timing of review by governmental authorities and the risks described in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 and its other filings with the Securities and Exchange Commission. 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: September 7, 2022

By: /s/ Marcio Souza

Marcio Souza

Chief Executive Officer