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 9, 2023

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.

On June 9, 2023, Praxis Precision Medicines, Inc. (the "Company") announced the outcomes from a recent end-of-Phase 2 meeting with the U.S. Food and Drug Administration regarding plans to advance ulixacaltamide into Phase 3 for essential tremor ("ET"). The key elements of the registration plan for ulixacaltamide are as follows:

- Use of the modified Activities of Daily Living 11 ("mADL11") as the primary endpoint is acceptable. In the Phase 2 Essential1 study, mADL11 was nominally significant (p=0.042). mADL11 comprises 11 elements of the TETRAS Activities of Daily Living, excluding social impact, individually scored from 0-3.
- Agreement to use a single dose of 60 mg for the Phase 3 trials
- Base case assumption confirmed for two Phase 3 trials, one of which will be a 12-week, parallel design study and one of which will be a 12-week randomized withdrawal study for stable responders
- Safety database required for a New Drug Application ("NDA") at the minimum required by ICH guidelines: 300 patients with six-months of exposure and 100 patients with one-year of exposure
- Agreement that the completed and planned clinical pharmacology and toxicology studies would be sufficient for submission of an NDA

The protocols for the Phase 3 trials are being finalized, and the Company intends to submit to the current Investigational New Drug Application shortly and to begin Phase 3 by year-end 2023.

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 clinical development of ulixacaltamide. 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, uncertainties inherent in clinical trials, the expected timing of submission for regulatory approval or review by governmental authorities and other risks as described in the Company's Annual Report on Form 10-K for the year ended December 31, 2022, its Quarterly Reports on Form 10-Q 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: June 9, 2023

By: /s/ Marcio Souza

Marcio Souza

Chief Executive Officer