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 2, 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 October 2, 2023, Praxis Precision Medicines, Inc. (the "Company") provided an update on its clinical portfolio at the Company's R&D Day. The Company shared the following updates on each of its clinical programs.

Ulixacaltamide

- Additional analysis from the Essential1 data set continues to support the design of the Phase 3 program for ulixacaltamide ("Essential3").
    - Data from Essential1 showed a meaningful difference in a minimum 3-point improvement in the modified Activities of Daily Living 11-point scale ("mADL11") between patients on ulixacaltamide versus placebo (55% v. 31%, p=0.023).
    - In the extension period of Essential1, which continued after Week 8 through Week 14, 64% of patients in the ulixacaltamide arm showed at least a 3-point improvement in mADL11 versus baseline. For patients transitioning from placebo at Week 8 onto ulixacaltamide, 69% achieved at least a 3-point improvement to baseline at Week 14.
    - Ulixacaltamide also demonstrated incremental benefit to patients on propranolol. 48% of patients on propranolol and ulixacaltamide in the Essential1 study achieved at least a 3-point improvement in mADL11 compared to 25% for patients on propranolol and placebo.
- mADL11 confirmed to serve as primary endpoint in both Phase 3 studies of Essential3 based on protocol feedback received from the U.S. Food and Drug Administration (the "FDA").
- The Company expects to submit a New Drug Application for ulixacaltamide in 2025.

PRAX-222

- Dosing for Part 1 of the EMBRAVE study is nearing completion, with patients receiving 1 mg doses once a month for four months at LeBonheur Children's Hospital in Memphis, Tennessee.
- No treatment related adverse events ("AEs") or serious adverse events ("SAEs") were observed in preliminary safety analysis as of the cutoff date of September 26, 2023.
- As of the cutoff date, data was evaluable for three of four dosing periods showing:
    - Patients achieved a 44% median reduction in seizures versus baseline, on top of best available standard of care.
    - Patients observed an increased number of days without seizures, achieving a median of 35% seizure free days over the dosing period compared to a baseline of 21% seizure free days.
    - All patients achieved significant seizure reduction after one dose.
- The Company intends to request a meeting in the fourth quarter of 2023 with the FDA to align on next steps for the program.

PRAX-628

- Additional data from the Phase 1 single ascending dose ("SAD") and multiple ascending dose ("MAD") study continue to reinforce the potential of PRAX-628 as a next generation precision anti-seizure medication ("ASM").
- Electroencephalogram ("EEG") data showed rapid and sustained activity in the brain when dosing PRAX-628 as compared to placebo.
- PRAX-628 achieved and sustained target therapeutic concentrations in excess of the equivalent Maximal Electroshock Seizure Model ("MES") EC_{50} after first administration.
- The Company expects to read out the results from the Phase 2 Photoparoxysmal Response ("PPR") study in the fourth quarter of 2023.

PRAX-562

- The Company is utilizing a decentralized recruiting and enrollment approach for its Phase 2 EMBOLD study for the treatment of pediatric patients with developmental and epileptic encephalopathies, with sites in both the United States and Europe.
- The Company expects topline results from the EMBOLD study in the first half of 2024.

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 its product candidates. 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; reported interim data from ongoing studies and trials differing materially from final data from preclinical studies and completed clinical trials; the expected timing of clinical trials, data readouts and the results thereof; submissions 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: October 2, 2023

By: /s/ Marcio Souza

Marcio Souza

Chief Executive Officer