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): December 4, 2025

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.

Ulixacaltamide

On December 4, 2025, Praxis Precision Medicines, Inc. (the "Company") announced the successful completion of its pre-New Drug Application ("NDA") meeting with the U.S. Food and Drug Administration (the "FDA"), including receipt of written feedback and an in-person meeting. The Company has gained alignment from the FDA on the content of the NDA and expects to complete its NDA submission in early 2026.

Relutrigine

On December 4, 2025, the Company announced positive results from the registrational cohort of the EMBOLD study evaluating relutrigine for the treatment of patients with SCN2A and SCN8A developmental and epileptic encephalopathies ("DEEs"), following a recommendation by the Data Monitoring Committee to stop the study early for efficacy.

On December 6, 2025, the Company shared the results of the EMBOLD study, demonstrating relutrigine was well-tolerated with rapid, significant and increasing seizure reduction over time with broad functional improvements across behavior, alertness, communication and overall status. The Company will meet with the FDA in the coming weeks to discuss next steps. The Company will make a determination of the timing for filing the NDA after the meeting.

The topline results for the EMBOLD study were as follows:

- Patients receiving relutrigine (n=51) experienced a 53% placebo-adjusted reduction in seizures over 16-weeks ($p<0.0002$).
- Patients achieved a 66% increase in motor seizure-free days ($p=0.034$).
- Both clinician and caregiver global impression scores showed statistically significant improvements, with most patients improving across both scales in alertness, communication, and seizure severity.
- There were no drug-related serious adverse events and treatment-related adverse events were predominantly mild and moderate.

Vormatrigine

On December 6, 2025, the Company shared the full results of the RADIANT study evaluating vormatrigine in patients with focal onset seizures ("FOS") or generalized epilepsy. The key results were as follows:

Focal Onset Seizures (n=62)

- Patients taking vormatrigine for 8 weeks on background anti-seizure medications saw a 54% median reduction in seizures.
- In week 1, 58% of patients achieved at least a 50% reduction in seizures, which increased to 61% by week 8.
- Increasing and sustained effect was observed, with FOS patients reaching 100% median weekly seizure reduction after 8 weeks and maintained through 16 weeks.
- Over 11% of patients experienced seizure freedom for the entire 8-week period and roughly one third of patients experienced seizure freedom for a consecutive 28-day period.

Generalized Epilepsy (n=3)

- Three patients with generalized epilepsy included in the cohort experienced a similar treatment effect as FOS patients, with rapid, durable seizure reduction.

The Company has completed recruiting for the POWER1 pivotal study in FOS and is on track to complete the POWER2 study in the second half of 2026. The monotherapy study, POWER3, is on track to begin in the first half of 2026.

Forward-Looking Statements

This Current Report 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 relutrigine and vormatrigine and the anticipated timing of regulatory submissions and interactions for ulixacaltamide and relutrigine. The forward-looking statements included in this Current Report 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, 2024, its Quarterly Report on Form 10-Q for the quarter ended June 30, 2025 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. 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: December 8, 2025

By: /s/ Marcio Souza

Marcio Souza

Chief Executive Officer