
**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 9, 2025

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

Delaware
(State or other jurisdiction
of incorporation)

001-39620
(Commission
File Number)

47-5195942
(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:

<u>Title of each class</u>	<u>Trade Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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.

Elsunersen

On December 9, 2025, Praxis Precision Medicines, Inc. (the “Company”) announced the completion of a Type C meeting with the U.S. Food and Drug Administration (the “FDA”) and agreement to immediately convert the EMBRAVE3 registrational study of elsunersen in early-onset SCN2A developmental and epileptic encephalopathy (“DEE”) into a single-arm study where all patients will receive elsunersen for 24 weeks, followed by an open-label extension.

Key Changes to EMBRAVE3

- The current study has been immediately converted from a double-blind, sham-controlled study to a single-arm, baseline-controlled study, enrolling 30 patients reduced from 40 patients.
- All patients currently in screening will be assigned to receive elsunersen.
- The primary analysis will be the change from baseline in countable motor seizures.

Update on EMBRAVE Study Status

The EMBRAVE Study Part A enrolled 9 patients randomized 3:1 to elsunersen or placebo/sham for 20 weeks, followed by a blinded transition to elsunersen for up to 2 years in an open-label extension. The Company expects to complete Part A and disclose the topline results in the first half of 2026.

Relutrigine

On December 11, 2025, the Company announced the completion of the planned discussion with the FDA, leading to the confirmation to file a New Drug Application for relutrigine in SCN2A and SCN8A DEEs in early 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 elsunersen and regulatory interactions and submissions for 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 11, 2025

By: /s/ Marcio Souza

Marcio Souza

Chief Executive Officer