Praxis Precision Medicines Provides Corporate Update and Reports Fourth Quarter and Full-Year 2025 Financial Results

February 19, 2026

Two new drug applications (NDA) for ulixacaltamide in essential tremor (ET) and for relutrigine in SCN2A and SCN8A developmental and epileptic encephalopathies (DEEs) have been submitted to the U.S. Food and Drug Administration (FDA)

Pre-launch activities for ulixacaltamide and relutrigine are underway and will accelerate through 2026

Essential3 results to be presented as an oral presentation at the American Academy of Neurology Annual Meeting

Cash and investments of $926 million as of December 31, 2025 and net proceeds of $621 million from January 2026 public offering fund operations into 2028
Conference call today, February 19, 2026 at 8:00 am E.T.

BOSTON, Feb. 19, 2026 (GLOBE NEWSWIRE) -- Praxis Precision Medicines, Inc. (NASDAQ: PRAX), a fully integrated, leading central nervous system (CNS) precision neuroscience biopharmaceutical company, today provided a corporate update and reported financial results for the fourth quarter and full-year 2025.

“After a landmark fourth quarter, filled with a breadth of clinical and regulatory advancements across our portfolio, we started 2026 with two NDA submissions for ulixacaltamide and relutrigine. Pending their expected positive reviews, we will be positioned to transition into a commercial company,” said Marcio Souza, president and chief executive officer. “The other two programs in the clinic, vormatrigine and elsunersen, will both have topline results in the first half of 2026, keeping us on track for additional NDA submissions in the next two years. Together, these four assets have a revenue potential of over $20 billion.”

Recent Highlights and Anticipated Milestones

Cerebrum™ Small Molecule Platform

Ulixacaltamide for Essential Tremor (ET): ET is one of the most common movement disorders, affecting approximately seven million patients in the U.S., yet it is inadequately managed and undertreated with no specific drugs developed for ET currently approved, as underscored by the interest from over 200,000 patients in the Essential3 program. Ulixacaltamide was the first investigational therapy to demonstrate positive results in a Phase 3 program in ET and was granted Breakthrough Therapy Designation by the FDA in December 2025.

- In October 2025, Praxis announced positive topline results from both Phase 3 studies in the ESSENTIAL3 program.
- Following a positive pre-NDA meeting with the FDA in December 2025, Praxis has submitted an NDA for the treatment of ET.
- Praxis will present several oral presentations and posters on ulixacaltamide at the upcoming American Academy of Neurology (AAN) Annual Meeting, taking place April 19 to 22, 2026 in Chicago, IL.
- Commercial preparations and pre-launch activities are well underway and will accelerate through 2026. Praxis is scaling its commercial organization, advancing launch readiness efforts, building inventory, and will initiate its disease awareness campaign in conjunction with the AAN meeting.

Relutrigine for DEEs: Relutrigine is a sodium channel modulator designed to precisely target the hyperexcitable state of sodium-channels, with therapeutic potential across developmental epilepsies. Relutrigine has been granted Breakthrough Therapy Designation and Orphan Drug Designation by the FDA.

- Praxis has submitted an NDA for relutrigine for the treatment of SCN2A and SCN8A DEEs based on the strong efficacy observed in the EMBOLD registrational cohort. The results of the trial were shared at the 2025 AES meeting.
- Enrollment in the EMERALD study in broad DEEs is progressing well and is expected to be fully enrolled in the second half of 2026. Assuming successful initial NDA approval of relutrigine, the EMERALD study, if positive, would serve as the basis for a supplemental NDA submission in 2027.
- Praxis has begun preparations for the commercial launch of relutrigine, including hiring key commercial roles, building sufficient inventory for launch and preparing and executing key pre-launch activities, which are expected to accelerate throughout 2026.

Vormatrigine for Focal Onset Seizures (FOS) and Generalized Epilepsy: An estimated 3.5 million people in the U.S. suffer from common epilepsies. Sodium channel therapy is the cornerstone of treatment for patients with epilepsy, yet currently approved drugs have significant safety and efficacy limitations. Vormatrigine is the most potent sodium-channel modulator ever developed for epilepsy and is designed to precisely target the hyperexcitable state of sodium-channels in adult common epilepsies.

- The full dataset from the RADIANT Phase 2 study were presented at the 2025 American Epilepsy Society Annual Meeting, positioning vormatrigine as a best-in-disease therapy. Study results showed its fast-acting efficacy without titration, sustained seizure reduction over longer treatment duration, seizure-freedom potential, and favorable DDI, tolerability and safety profiles with once-daily dosing.
- The POWER1 Phase 3 study for FOS completed enrollment and exceeded its original target; topline results are expected in the second quarter of 2026.
- POWER2, the second Phase 3 study for vormatrigine in FOS, is enrolling patients, with completion expected in the second half of 2026 and topline results anticipated in 2027.
- The POWER3 study to evaluate vormatrigine as a monotherapy is on track to commence in the first half of 2026.

Solidus™ Antisense Oligonucleotide (ASO) Platform

- **Elsunersen for early-seizure-onset SCN2A DEE:** SCN2A Gain-of-function (GoF)-DEE is a rare, genetic epilepsy characterized by early-onset seizures and severe impact on development.
  - The EMBRAVE Part A Phase 1/2 study evaluating SCN2A early seizure onset patients with a 3:1 drug to sham arm evaluating safety and seizure reduction is on track for topline results in the first half of 2026.
  - In December 2025, Praxis shared that after a favorable meeting with the FDA there was agreement to update the EMBRAVE3 registrational trial design by removing the sham control arm. Enrollment is underway, with topline results expected in 2027.
- Praxis remains on track to nominate a development candidate for each of its three early stage ASO therapeutic initiatives in the first half of 2026:
  - PRAX-080 is focused on targeting PCDH19 mosaic expression disorder
  - PRAX-090 is designed to address SYNGAP1 loss-of-function (LoF) mutations, a leading cause of severe intellectual disability and epilepsy in DEEs.
  - PRAX-100 targets SCN2A LoF mutations, the predominant genetic link to de novo autism spectrum disorders.

Corporate Updates:
In January 2026, Praxis announced updates to its board of directors, key promotions and additions to the company:

- Jeffrey B. Kindler and Stuart Arbuckle joined the Board of Directors.
- Promoted Megan Sniecinski to Chief Operating Officer and Steven Petrou, Ph.D. to President of Research & Development.
- Appointed Orrin Devinsky, M.D., a global epilepsy leader, as Head of Clinical Strategy.

Fourth Quarter and Full Year 2025 Financial Results:
As of December 31, 2025, Praxis had $926.1 million in cash, cash equivalents and marketable securities, compared to $469.5 million in cash, cash equivalents and marketable securities as of December 31, 2024. This increase of $456.6 million was primarily due to net proceeds from Praxis' October 2025 follow-on public offering and net proceeds from at-the-market sales of common stock, partially offset by cash used in operations. The Company's cash, cash equivalents and marketable securities as of December 31, 2025, together with $621.2 proceeds from its January 2026 follow on public offering, are expected to fund operations into 2028.

Research and development expenses were $77.5 million for the fourth quarter of 2025, compared to $56.3 million for the fourth quarter of 2024. Research and development expenses were $267.1 million for the year ended December 31, 2025, compared to $152.4 million for the year ended December 31, 2024. The increase in research and development expenses for full year 2025 of $114.7 million was primarily attributable to an increase of $91.9 million in Praxis' Cerebrum™ platform, an increase of $15.3 million in personnel related costs and an increase of $5.0 million in Praxis' Solidus™ platform.

General and administrative expenses were $19.5 million for the fourth quarter of 2025, compared to $15.1 million for the fourth quarter of 2024. General and administrative expenses were $59.1 million for the year ended December 31, 2025, compared to $56.3 million for the year ended December 31, 2024. The increase in general and administrative expenses for full year 2025 of $2.8 million was primarily attributable to an increase in professional fees.

Praxis incurred a net loss of $88.9 million for the fourth quarter of 2025, including $9.9 million of stock-based compensation expense, compared to $58.7 million for the fourth quarter of 2024, including $8.6 million of stock-based compensation expense. Praxis reported a net loss of $303.3 million for the year ended December 31, 2025, including $33.9 million of stock-based compensation expense, compared to a net loss of $182.8 million for the year ended December 31, 2024, including $41.4 million of stock-based compensation expense.

As of December 31, 2025, Praxis had 25.2 million shares of common stock outstanding.

Conference Call
Praxis will discuss fourth quarter and full year 2025 financial results and business highlights on a conference call taking place today, February 19 at 8:00 am ET, which can be accessed by visiting this registration link. The live audio webcast will also be available through the Events & Presentations page of the Investors + Media section of the Company's website .

About Ulixacaltamide
Ulixacaltamide is a differentiated and highly selective small molecule inhibitor of T-type calcium channels designed to block abnormal neuronal burst firing in the Cerebello-Thalamo-Cortical (CTC) circuit correlated with tremor activity. Ulixacaltamide has received Breakthrough Therapy Designation from the FDA and is the most advanced program within Praxis' Cerebrum™ small molecule platform.

About Vormatrigine
Vormatrigine is a next-generation, functionally selective small molecule targeting the hyperexcitable state of sodium-channels in the brain that is currently being developed as a once daily, oral treatment for adult focal onset seizures and generalized epilepsy. Preclinical data demonstrates vormatrigine is differentiated from standard of care, with the potential to be best-in-class for focal epilepsy. In vitro, vormatrigine has demonstrated superior selectivity for disease-state NaV channel hyperexcitability. In vivo studies of vormatrigine have demonstrated unprecedented potency in the maximal electroshock seizure (MES) model, a highly predictive translational model for efficacy in focal epilepsy. Data from patients in the RADIANT study demonstrated a robust seizure reduction and generally safe and well tolerated profile. To learn more about the POWER1 and POWER2 studies, please visit POWER studies.

About Relutrigine
Relutrigine is a first-in-class small molecule in development for the treatment of developmental and epileptic encephalopathies (DEEs) as a preferential inhibitor of persistent sodium current, shown to be a key driver of seizure symptoms in severe DEEs. Relutrigine's mechanism of precision sodium channel (NaV) modulation is consistent with superior selectivity for disease-state NaV channel hyperexcitability. In vivo studies of relutrigine have demonstrated dose-dependent inhibition of seizures up to complete control of seizure activity in SCN2A, SCN8A and other DEE mouse models. Relutrigine has been generally well-tolerated in three Phase 1 studies and has demonstrated biomarker changes indicative of NaV channel modulation. Data from cohort 1 of the Phase 2 EMBOLD study demonstrated a well-tolerated, robust, short- and long-term improvement in motor seizures in a heavily pre-treated population, alongside maintained seizure freedom in some patients with SCN2A- and SCN8A-DEE. Relutrigine has received Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation from the FDA for the treatment of SCN2A-DEE, SCN8A-DEE and Dravet syndrome; as well as Breakthrough Therapy Designation (BTD), and ODD from the European Medicines Agency for the treatment of SCN2A-DEE and SCN8A-DEE. To learn more about the EMERALD study, please visit Emerald | Resilience Studies.

About Elsunersen
Elsunersen is an antisense oligonucleotide (ASO) designed to selectively decrease SCN2A gene expression, directly targeting the underlying cause of early-seizure-onset SCN2A-DEE to treat seizures and other symptoms in patients with gain-of-function SCN2A mutations. In vitro studies of elsunersen have demonstrated reduction in both SCN2A gene expression and protein levels. In vivo, elsunersen has demonstrated significant, dose-dependent reduction in seizures, improvement in behavioral and locomotor activity and increased survival in SCN2A mouse models, with potential to be the first disease-modifying treatment for SCN2A-DEE. Elsunersen has received ODD and RPDD from the FDA, and ODD and PRIME designations from the European Medicines Agency for the treatment of SCN2A-DEE. The elsunersen program is ongoing under a collaboration with Ionis Pharmaceuticals, Inc., and RogCon, Inc. To learn more about the EMBRAVE3 study, please visit Embrave | Resilience Studies.

About Praxis
Praxis Precision Medicines is a fully integrated, leading central nervous system (CNS) precision neuroscience biopharmaceutical company, translating insights from genetic epilepsies into the development of therapies for CNS disorders characterized by neuronal excitation-inhibition imbalance. Praxis is applying genetic insights to the discovery and development of therapies for rare and more prevalent neurological disorders through our proprietary small molecule platform, Cerebrum™, and antisense oligonucleotide (ASO) platform, Solidus™, using our understanding of shared biological targets and circuits in the brain. Praxis has established a diversified, multimodal CNS portfolio including multiple programs across movement disorders and epilepsy, with four late-stage product candidates. For more information, please visit www.praxismedicines.com and follow us on Facebook, LinkedIn and X/Twitter.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995 and other federal securities laws, including express or implied statements regarding Praxis' future expectations, plans and prospects, including, without limitation, statements regarding the anticipated timing of clinical trials, the development of Praxis' product candidates and plans to initiate new clinical programs, the anticipated timing of regulatory submissions and interactions, potential market opportunity and commercial potential of Praxis' product candidates and our projected cash runway, as well as other statements containing the words "anticipate," "believe," "continue," "could," "endeavor," "estimate," "expect," "anticipate," "intend," "may," "might," "plan," "potential," "predict," "project," "seek," "should," "target," "will" or "would" and similar expressions that constitute forward-looking statements under the Private Securities Litigation Reform Act of 1995.

The express or implied forward-looking statements included in this press release are only predictions and are subject to a number

of risks, uncertainties and assumptions, including, without limitation: uncertainties inherent in clinical trials; the expected timing of clinical trials, data readouts and the results thereof, and submissions for regulatory approval or review by governmental authorities; regulatory approvals to conduct trials; and other risks concerning Praxis' programs and operations as described in its Annual Report on Form 10-K for the year ended December 31, 2025 to be filed and other filings made with the Securities and Exchange Commission. Although Praxis' forward-looking statements reflect the good faith judgment of its management, these statements are based only on information and factors currently known by Praxis. As a result, you are cautioned not to rely on these forward-looking statements. Any forward-looking statement made in this press release speaks only as of the date on which it is made. Praxis undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

PRAXIS PRECISION MEDICINES, INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands)
(Unaudited)

	December 31, 2025	December 31, 2024
Assets		
Cash and cash equivalents	$ 357,329	$ 215,372
Marketable securities	568,759	254,156
Prepaid expenses and other current assets	11,580	11,805
Property and equipment, net	147	230
Operating lease right-of-use assets	92	1,131
Other non-current assets	—	416
Total assets	$ 937,907	$ 483,110
Liabilities and stockholders' equity		
Accounts payable	$ 24,628	$ 12,528
Accrued expenses	35,033	23,763
Operating lease liabilities	110	1,369
Common stock	15	14
Additional paid-in capital	2,017,566	1,281,522
Accumulated other comprehensive gain	563	654
Accumulated deficit	(1,140,008)	(836,740)
Total liabilities and stockholders' equity	$ 937,907	$ 483,110

PRAXIS PRECISION MEDICINES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2025	2024	2025	2024
Collaboration revenue	$ —	$ 7,463	$ —	$ 8,553
Operating expenses:				
Research and development	77,506	56,288	267,115	152,413
General and administrative	19,538	15,131	59,083	56,305
Total operating expenses	97,044	71,419	326,198	208,718
Loss from operations	(97,044)	(63,956)	(326,198)	(200,165)
Other income:				
Other income, net	8,133	5,277	22,930	17,346
Total other income	8,133	5,277	22,930	17,346
Net loss	$ (88,911)	$ (58,679)	$ (303,268)	$ (182,819)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.50)	$ (2.94)	$ (13.48)	$ (10.21)
Weighted average common shares outstanding, basic and diluted	25,407,069	19,980,179	22,504,676	17,906,794

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