
**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): March 04, 2026

PepGen Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-41374
(Commission File Number)

85-3819886
(IRS Employer
Identification No.)

321 Harrison Avenue
8th Floor
Boston, Massachusetts
(Address of Principal Executive Offices)

02118
(Zip Code)

Registrant's Telephone Number, Including Area Code: (781) 797-0979

(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 | Trading Symbol(s) | Name of each exchange on which registered |
|--|----------------------|---|
| Common stock, par value \$0.0001 per share | PEPG | 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 2.02 Results of Operations and Financial Condition.

On March 4, 2026, PepGen Inc. (the "Company") announced its financial results for the year ended December 31, 2025 and issued a press release titled "PepGen Reports Fourth Quarter and Year-End 2025 Financial Results and Recent Corporate Highlights". A copy of the press release is furnished as Exhibit 99.1.

The information provided in this Current Report on Form 8-K (this "Form 8-K"), including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On March 4, 2026, the Company announced that it received a partial clinical hold notice from the U.S. Food and Drug Administration on the FREEDOM2-DM1 Phase 2 multiple ascending dose ("MAD"), randomized, placebo-controlled clinical trial of PGN-EDODM1 in patients with myotonic dystrophy type 1 ("DM1"). A copy of the press release issued in connection with the announcement is attached as Exhibit 99.2 to this form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit Number | Description |
|-----------------------|---|
| 99.1 | Press Release issued by PepGen Inc. on March 4, 2026 titled "PepGen Reports Fourth Quarter and Year-End 2025 Financial Results and Recent Corporate Highlights" |
| 99.2 | Press Release issued by PepGen Inc. on March 4, 2026 titled "PepGen Announces Regulatory Updates on FREEDOM2" |
| 104 | Cover Page Interactive Data File (embedded within Inline XBRL document) |

SIGNATURES

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.

PepGen Inc.

Date: March 4, 2026

By: /s/ Noel Donnelly
Noel Donnelly, Chief Financial Officer

PepGen Reports Fourth Quarter and Year-End 2025 Financial Results and Recent Corporate Highlights

– FREEDOM2-DM1 5 mg/kg cohort data expected in Q1 2026 –

– Patient dosing in the FREEDOM2 10 mg/kg cohort is proceeding in Canada and the UK, with data expected in 2H 2026 –

– FREEDOM2 trial open in South Korea, Australia, and New Zealand –

– Well-funded with \$148.5M of cash as of December 31, 2025, sufficient to fund operations into the second half of 2027 –

BOSTON— March 4, 2026-- PepGen Inc. (Nasdaq: PEPG), a clinical-stage biotechnology company advancing the next generation of oligonucleotide therapies with the goal of transforming the treatment of severe neuromuscular and neurological diseases, today reported financial results for the quarter and year-ended December 31, 2025, and recent corporate highlights.

“2025 was a transformative year for PepGen as the Phase 1 FREEDOM trial delivered compelling data that set a new benchmark for splicing correction in DM1, reinforced our conviction in PGN-EDODM1 as a potential best-in-class treatment, and further demonstrated the differentiated potential of our EDO platform,” said James McArthur, PhD, President and Chief Executive Officer of PepGen. “After a single dose, we observed robust target engagement beginning at the lowest dose of 5 mg/kg — a finding that exceeded our expectations and underscored the potency of our drug candidate. PGN-EDODM1 was generally well-tolerated across doses, and based on the totality of FREEDOM data, we believe that doses of 10 mg/kg could potentially offer a best-in-class treatment option for people living with this serious disease.”

Dr. McArthur continued: “As we prepare for the 5 mg/kg dose cohort readout from our ongoing randomized, placebo-controlled multiple ascending dose Phase 2 FREEDOM2 study later this quarter, we are focused on building upon the robust muscle oligonucleotide levels and splicing correction observed in FREEDOM, with the goal of translating sustained exposure into meaningful functional benefit. Following the Data Safety Monitoring Board’s recommendation to dose escalate, we are actively dosing the 10 mg/kg cohort in FREEDOM2 – four patients have been dosed, receiving up to two doses. PepGen is entering this new year with strong momentum and a clear path toward potentially delivering a meaningful new treatment for the DM1 community.”

Recent Program Updates

PGN-EDODM1: Myotonic Dystrophy Type 1 (DM1)

- **FREEDOM2 Phase 2 Multiple Ascending Dose (MAD) Randomized, Placebo-Controlled Clinical Trial of PGN-EDODM1:**
 - The Company expects to report results from the 5 mg/kg cohort of the FREEDOM2 trial in the first quarter of 2026.
 - After reviewing safety data from the 5 mg/kg cohort, the Data Safety Monitoring Board (DSMB) recommended escalating to the 10 mg/kg dose. PepGen has since dosed 50% of
-

patients (4/8) in the 10 mg/kg cohort with up to two doses. The Company remains on track to report results from the 10 mg/kg cohort in the second half of 2026.

- o Informed by the prior FREEDOM results, PepGen has amended the FREEDOM2 protocol to provide the option to dose up to 12.5 mg/kg.
- o Patients from the FREEDOM and FREEDOM2 studies in Canada are continuing into the Open Label Extension (OLE) study. The Company has received regulatory clearance for the OLE study in the UK and intends to open the OLE study in all geographies where FREEDOM2 is open.
- o The Company has recently received regulatory clearance to initiate the FREEDOM2 trial in South Korea, Australia, and New Zealand. Sites are currently enrolling in Canada, the UK and South Korea, with plans to open sites in New Zealand and Australia.
- o The U.S. Food and Drug Administration (FDA) has placed a partial clinical hold on the FREEDOM2 study. The partial clinical hold questions raised by FDA relate to previously submitted preclinical pharmacology and toxicology studies. The partial clinical hold did not cite any questions regarding blinded clinical data from the Phase 1 FREEDOM study previously submitted to the FDA in order to initiate the FREEDOM2 study in the U.S. The Company is committed to working with the FDA to address the Agency's questions as quickly as possible.

- **Other FREEDOM Updates:**

- o In October 2025, PepGen's data were featured in two oral presentations at the 30th Annual International Congress of the World Muscle Society (WMS). One presentation included previously reported positive FREEDOM-DM1 Phase 1 clinical data.
- o In October 2025, the Company gave an oral presentation at the Oligonucleotide Therapeutics Society (OTS) Annual Meeting. The presentation reviewed the use of its Enhanced Delivery Oligonucleotide (EDO) Platform to develop a treatment for DM1 and included a review of the FREEDOM clinical data.

2026 MDA Conference Update

The Company will present unblinded final results from FREEDOM-DM1 — its Phase 1, placebo-controlled single ascending dose study of PGN-EDODM1 in DM1 adult patients — in oral and poster presentations at the 2026 Muscular Dystrophy Association (MDA) Clinical & Scientific Conference, being held March 8–11, 2026 in Orlando, Florida.

Key study findings include:

Efficacy: PGN-EDODM1 demonstrated greater than dose-proportional increases in muscle tissue concentration and splicing correction across all doses at Day 28. Mean splicing correction reached unprecedented levels after a single dose, achieving 12.3%, 29.1%, and 53.7% at 5 mg/kg (n=6), 10 mg/kg (n=5), and 15 mg/kg (n=6), respectively.

Safety: PGN-EDODM1 was generally well-tolerated across all doses; treatment-emergent adverse events (TEAEs) were mild to moderate, transient, and required no intervention (except one patient in the 15 mg/kg cohort, managed with oral antihistamines). No electrolyte-related TEAEs were observed, and magnesium levels remained within normal range across all doses. No renal biomarker-related TEAEs

were observed at 5 or 10 mg/kg. Post-unblinding, transient moderate albuminuria increases at the 15 mg/kg dose and transient mild albuminuria increases at 10 mg/kg were apparent — both resolving to normal within two to seven days with no clinical symptoms or need for intervention.

Following the conference, the presentations presented at the 2026 MDA Clinical & Scientific Conference will be available on PepGen's website under Scientific Publications.

Corporate Updates

- In December 2025, PepGen appointed Joseph Vittiglio, Esq., as Chief Business and Legal Officer. Mr. Vittiglio brings more than two decades of executive leadership experience across legal, compliance, corporate development, and corporate governance within public biotechnology companies. He joins PepGen after providing consulting support to the Company in 2025.
- In November 2025, the Company announced that the United States Patent and Trademark Office (USPTO) has issued the Company a new composition of matter patent covering PGN-EDODM1, which leverages PepGen's proprietary EDO platform, including its unique peptide and linker chemistry. This newly issued composition of matter patent, which serves as a cornerstone of the Company's expanding patient portfolio, is expected to provide exclusivity for PGN-EDODM1 in the United States into second half of 2042, with the possibility of patent term extension following a potential new drug application and approval by FDA of PGN-EDODM1.

Financial Results for the Three Months and Year Ended December 31, 2025

- **Cash, Cash Equivalents and Marketable Securities** were \$148.5 million as of December 31, 2025. Based on currently planned operations, the Company believes that its existing cash, cash, equivalents, and marketable securities will be sufficient to fund its operations into the second half of 2027.
- **Research and Development Expenses** were \$13.9 million for the three months ended December 31, 2025, compared to \$19.0 million for the same period in 2024. Research and development expenses were \$71.0 million for the year ended December 31, 2025, compared to \$76.5 million for the same period in 2024.
- **General and Administrative Expenses** were \$5.9 million for the three months ended December 31, 2025, compared to \$5.4 million for the same period in 2024. General and administrative expenses were \$22.6 million for the year ended December 31, 2025, compared to \$21.3 million for the same period in 2024.
- **Net Loss** was \$18.3 million, or \$(0.27) basic and diluted net loss per share, for the three months ended December 31, 2025, compared to \$22.2 million, or \$(0.68) basic and diluted net loss per share, for the same period in 2024. Net loss was \$89.7 million, or \$(2.12) basic and diluted net loss per share, for the year ended December 31, 2025, compared to \$90.0 million, or \$(2.85) basic and diluted net loss per share, for the same period in 2024. PepGen had approximately 68,874,944 shares outstanding as of December 31, 2025.

About PGN-EDODM1

PGN-EDODM1, PepGen's investigational candidate in development for the treatment of DM1, utilizes the Company's proprietary EDO technology to deliver a therapeutic oligonucleotide that is designed to restore the normal splicing function of MBNL1, a key RNA splicing protein. PGN-EDODM1 addresses the deleterious effects of cytosine-uracil-guanine (CUG) repeat expansion in

the dystrophin protein kinase (DMPK) transcripts which sequester MBNL1, by binding to the pathogenic CUG trinucleotide repeat expansion present in the DMPK transcripts, and disrupting the binding between the CUG repeat expansion and MBNL1. PepGen believes this innovative therapeutic approach may have considerable advantages over oligonucleotide modalities that rely on knockdown or degradation of the DMPK transcripts as it will allow the DMPK transcripts to continue to perform their normal function within the cell, while also liberating MBNL1 to correct downstream mis-splicing events. The U.S. Food and Drug Administration has granted PGN-EDODM1 both Orphan Drug and Fast Track Designations for the treatment of patients with DM1. The European Medicines Agency (EMA) has recently granted Orphan Designation for PGN-EDODM1.

About PepGen

PepGen Inc. is a clinical-stage biotechnology company developing the next generation of oligonucleotide therapies with the goal of transforming the treatment of severe neuromuscular and neurological diseases. PepGen's Enhanced Delivery Oligonucleotide (EDO) platform is founded on over a decade of research and development and leverages cell-penetrating peptides to improve the uptake and activity of conjugated oligonucleotide therapeutics. Using these EDO peptides, the Company is generating a pipeline of oligonucleotide therapeutic candidates designed to target the root cause of serious diseases.

For more information, please visit PepGen.com. Follow PepGen on *LinkedIn* and *X*.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, statements regarding the therapeutic potential and safety profile of PGN-EDODM1 based on data from the 5, 10 and 15 mg/kg cohorts of the FREEDOM-DM1 study, our expectations regarding the potential for significant correction of mis-splicing with more doses of PGN-EDODM1 over a longer treatment period to potentially provide improved functional benefit for patients with DM1, the design and conduct of clinical trials with our candidates, including expected timelines for the initial data report from our FREEDOM2-DM1 trial and the potential to extend dosing to the 12.5 mg/kg dose level, the potential for any functional improvements that may result from robust splicing correction with PGN-EDODM1, dose-dependent increases in splicing suggesting that PGN-EDODM1 is getting into the muscle and effectively binding to the target, the potential for PGN-EDODM1 to offer a best-in-class treatment option, the potential for future patent term extension, forecasts relating to our cash runway, and ongoing and planned regulatory interactions and ongoing and planned regulatory interactions, including the potential timing and successful resolution of questions from the FDA relating to the partial clinical hold.

Any forward-looking statements in this press release are based on current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to risks related to:

delays or failure to successfully initiate or complete our ongoing and planned development activities for our product candidates, including PGN-EDODM1; our ability to enroll patients in our clinical trials, including FREEDOM2; that our interpretation of clinical and preclinical study results may be incorrect, or that we may not observe the levels of therapeutic activity in clinical testing that we anticipate based on prior clinical or preclinical results, including for PGN-EDODM1; our product candidates, including PGN-EDODM1, may not be safe and effective or otherwise demonstrate safety and efficacy in our clinical trials; adverse outcomes from our regulatory interactions, including delays in regulatory review, clearance to proceed with planned clinical studies or approval by regulatory authorities with respect to our investigational drug candidates, including release of the partial clinical hold placed by FDA on the FREEDOM2 study, or other regulatory feedback requiring modifications to our development programs, , including release of the partial clinical hold or clearance to commence planned clinical studies of our product candidates, or other regulatory feedback requiring modifications to our development programs, including in each case with respect to our FREEDOM2 program; changes in regulatory framework that are out of our control; unexpected increases in the expenses associated with our development activities or other events that adversely impact our financial resources and cash runway; and our dependence on third parties for some or all aspects of our product manufacturing, research and preclinical and clinical testing. Additional risks concerning PepGen's programs and operations are described in our most recent reports filed with the SEC. PepGen explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

This release discusses PGN-EDODM1, an investigational therapy that has not been approved for use in any country, and is not intended to convey conclusions about its efficacy or safety. There is no guarantee that PGN-EDODM1 or any other investigational therapy will successfully complete clinical development or gain regulatory authority approval.

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Condensed Consolidated Statements of Operations
(unaudited, in thousands)

| | Twelve Months Ended December 31, | | Three Months Ended December 31, | |
|---|-------------------------------------|-------------------|------------------------------------|-------------------|
| | 2025 | 2024 | 2025 | 2024 |
| Operating expenses: | | | | |
| Research and development | \$ 71,043 | \$ 76,478 | \$ 13,851 | \$ 18,961 |
| General and administrative | 22,569 | 21,261 | 5,854 | 5,384 |
| Total operating expenses | \$ 93,612 | \$ 97,739 | \$ 19,705 | \$ 24,345 |
| Operating loss | \$(93,612) | \$(97,739) | \$(19,705) | \$(24,345) |
| Other income (expense) | | | | |
| Interest income | 4,017 | 7,142 | 1,419 | 1,460 |
| Other income (expense), net | (11) | (1) | (5) | 26 |
| Total other income, net | 4,006 | 7,141 | 1,414 | 1,486 |
| Net loss before income tax | \$(89,606) | \$(90,598) | \$(18,291) | \$(22,859) |
| Income tax (expense) benefit | (49) | 617 | (49) | 617 |
| Net loss | \$(89,655) | \$(89,981) | \$(18,340) | \$(22,242) |
| Net loss per share, basic and diluted | \$(2.12) | \$(2.85) | \$(0.27) | \$(0.68) |
| Weighted-average common shares outstanding, basic and diluted | 42,221,808 | 31,583,073 | 68,790,477 | 32,602,981 |

Condensed Consolidated Balance Sheets
(unaudited, in thousands)

| | December 31, 2025 | December 31, 2024 |
|--|------------------------------|------------------------------|
| Assets | | |
| Cash, cash equivalents and marketable securities | \$ 148,456 | \$ 120,191 |
| Other assets | 25,451 | 30,692 |
| Total assets | <u>\$ 173,907</u> | <u>\$ 150,883</u> |
| Liabilities and stockholders' equity | | |
| Liabilities | \$ 26,463 | \$ 32,263 |
| Stockholders' equity | 147,444 | 118,620 |
| Total liabilities and stockholders' equity | <u>\$ 173,907</u> | <u>\$ 150,883</u> |

PepGen Announces Regulatory Updates on FREEDOM2

- U.S. FDA places FREEDOM2 trial on partial clinical hold related to preclinical pharmacology and toxicology -
- Received regulatory clearance to initiate FREEDOM2 in South Korea, Australia, and New Zealand and dosing of the 10 mg/kg cohort continues in the UK and Canada -
- PepGen reiterates guidance for reporting data from the FREEDOM2 5 mg/kg cohort in Q1 2026 and from the 10 mg/kg cohort in 2H 2026 -

BOSTON—March 4, 2026— PepGen Inc. (Nasdaq: PEPG), a clinical-stage biotechnology company advancing the next generation of oligonucleotide therapies to treat severe neuromuscular and neurological diseases, today announced regulatory updates related to the FREEDOM2 trial.

The U.S. Food and Drug Administration (FDA) has placed a partial clinical hold on the FREEDOM2-DM1 Phase 2 multiple ascending dose (MAD), randomized, placebo-controlled clinical trial of PGN-EDODM1 in patients with myotonic dystrophy type 1 (DM1). The partial clinical hold did not cite any questions regarding blinded clinical data from the Phase 1 FREEDOM study previously submitted to the FDA in order to initiate the FREEDOM2 study in the U.S. As part of its ongoing dialogue with the FDA, the Company is submitting additional analyses, including the recently unblinded FREEDOM data, and is committed to working with the FDA to address their questions as quickly as possible.

PepGen was recently cleared to open the FREEDOM2 study in New Zealand, Australia, and South Korea.

Following the Data Safety Monitoring Board's recommendation to dose escalate, the FREEDOM2 trial is dosing patients at 10 mg/kg in Canada and the UK. No U.S. patients have been enrolled in FREEDOM2. Patients from the FREEDOM and FREEDOM2 studies in Canada are continuing into the Open Label Extension (OLE) study. The Company has received regulatory clearance for the OLE study in the UK and intends to open the OLE study in all geographies where FREEDOM2 is open.

The Company expects to report data from the 5 mg/kg cohort of FREEDOM2 in the first quarter of 2026, and from the 10 mg/kg cohort in the second half of 2026.

About PGN-EDODM1

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Any forward-looking statements in this press release are based on current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to risks related to: delays or failure to successfully initiate or complete our ongoing and planned development activities for PGN-EDODM1; our ability to enroll patients in our clinical trials, including FREEDOM2; that our interpretation of clinical and preclinical study results may be incorrect, or that we may not observe the levels of therapeutic activity in clinical testing that we anticipate based on prior clinical or preclinical results for PGN-EDODM1; that PGN-EDODM1 may not be safe and effective or otherwise demonstrate safety and efficacy in our clinical trials; adverse outcomes from our regulatory interactions, including delays in regulatory review, clearance to proceed or approval by regulatory authorities with respect to our programs, including release of the partial clinical hold or clearance to commence planned clinical studies of our product candidates, or other regulatory feedback requiring modifications to our development programs, including in each case with respect to our FREEDOM2 program; changes in regulatory framework that are out of our control; unexpected increases in the expenses associated with our development activities or other events that adversely impact our financial resources and cash runway; and our dependence on third parties for some or all aspects of our product manufacturing, research and preclinical and clinical testing. Additional risks concerning PepGen's programs and operations are described in our most recent reports filed with the SEC. PepGen explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

This release discusses PGN-EDODM1, an investigational therapy that has not been approved for use in any country, and is not intended to convey conclusions about its efficacy or safety. There is no guarantee that PGN-EDODM1 or any other investigational therapy will successfully complete clinical development or gain regulatory authority approval.

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