PepGen Reports Third Quarter 2026 Financial Results and Recent Corporate Highlights

November 10, 2026

– Positive FREEDOM2-DM1 10 mg/kg cohort results demonstrated highest reported splicing correction and improvements across multiple functional measures –

– 12.5 mg/kg FREEDOM2-DM1 cohort fully enrolled, with participants having received up to three doses; results expected in 1H 2027 –

– FREEDOM-OLE 10 mg/kg safety and 5 mg/kg clinical data expected in January 2027 –

– Well-funded with $104.8M of cash as of September 30, 2026, sufficient to fund operations into 2028 –

BOSTON--(BUSINESS WIRE)--Nov. 10, 2026-- PepGen Inc. (Nasdaq: PEPG), a clinical-stage biotechnology company pioneering oligonucleotide therapies with the potential to transform the treatment of rare genetic diseases, today reported financial results and recent corporate highlights for the quarter ended September 30, 2026. PepGen also released today positive topline results from the 10 mg/kg multiple ascending dose cohort of the ongoing Phase 2 FREEDOM2-DM1 trial (NCT06667453) evaluating PGN-EDODM1 in patients with myotonic dystrophy type 1 (DM1), a rare, progressive, and multisystemic genetic disease.

"The positive 10 mg/kg cohort results we announced today were made possible by our team's focused execution," said James McArthur, Ph.D., President and Chief Executive Officer of PepGen. "We are very confident in PGN-EDODM1's potential to deliver meaningful benefit to the DM1 community, and our company ended the quarter in a strong position to advance the program to the third and highest dose cohort, which is fully enrolled."

Recent Program Updates

PGN-EDODM1: Myotonic Dystrophy Type 1 (DM1)

- **FREEDOM2-DM1 Phase 2 Multiple Ascending Dose (MAD) 10 mg/kg Results:**
  - Topline data from the 10 mg/kg dose cohort demonstrated a mean splicing correction of 46.5%, the highest reported to date in a multiple dose study. Five of six participants demonstrated greater than 20% splicing improvement, and four participants had greater than 50% splicing improvement at Week 13.
  - The data also showed notable improvements across multiple functional measures including video Hand Opening Time (vHOT), hand grip strength, 10-Meter Walk/Run Test (10MWRT), and Timed Up and Go (TUG).
  - PGN-EDODM1 continued to be generally well tolerated at 10 mg/kg in the FREEDOM2 study with no treatment discontinuations, no serious or severe adverse events (SAE), and no dose-limiting toxicities (DLT) reported.
  - Read the full release here.
- **FREEDOM2-DM1 and FREEDOM-OLE Next Steps:**
  - Based on the review of available safety data from the 10 mg/kg MAD cohort and FREEDOM-OLE (OLE), an independent Data and Safety Monitoring Board (DSMB), recommended advancing the FREEDOM2 trial into the third and highest dose cohort (12.5 mg/kg). The 12.5 mg/kg cohort of FREEDOM2 is fully enrolled with all participants having received up to three doses and results are expected in the first half of 2027.
  - The DSMB also approved dose escalation in the OLE from 5 mg/kg to 10 mg/kg. To date, >35 doses at 10 mg/kg and 100 doses at 5 mg/kg have been delivered and 19 participants are now enrolled in the OLE. Furthermore, there have been no SAEs, no DLTs, with one discontinuation occurring due to hypersensitivity reaction. Interim 10 mg/kg OLE safety and 5 mg/kg OLE clinical data are expected in January 2027.
  - Building upon the positive results seen at 10 mg/kg, PepGen plans to initiate an expansion cohort, running in parallel to Cohort 3, to generate longer term (up to 9 months) data.
- **PGN-EDODM1 Regulatory Updates:**

- Data from the FREEDOM2 and FREEDOM-OLE studies (NCT07220603) are expected to support an end-of-Phase 2 (EOP2) meeting in the second half of 2027 pending removal of the partial clinical hold.
- In March 2026, PepGen announced that the U.S. Food and Drug Administration (FDA) issued a partial clinical hold on the FREEDOM2 study citing nonclinical findings in mice. We are conducting nonclinical mouse studies and remain actively engaged with the FDA about conducting additional nonclinical mouse studies designed to generate data to respond to the FDA's questions.
- In October 2026, under the currently open U.S. FDA IND, the FDA selected PGN-EDODM1 for its CMC Development and Readiness Pilot (CDRP) program. This program allows for enhanced regulatory engagement with the FDA to de-risk CMC development through structured, CDRP-enabled interactions. In addition, the program is designed to accelerate alignment on critical manufacturing development strategies ahead of Phase 3 and NDA submission.

Corporate Updates

- In September 2026, PepGen presented PGN-EDODM1 data at the 27th Annual Neuromuscular Study Group Scientific Meeting (NMSG) and the 31st Annual Congress of the World Muscle Society (WMS). The data were featured in oral and poster presentations at both NMSG and WMS. Paul Streck, M.D., MBA, PepGen's Executive Vice President, Head of Research and Development, presented FREEDOM and FREEDOM2 clinical data.

Financial Results for the Three Months Ended September 30, 2026

- **Cash, Cash Equivalents and Marketable Securities** were $104.8 million as of September 30, 2026. Based on currently planned operations, PepGen believes that its existing cash, cash equivalents, and marketable securities will be sufficient to fund its operations into 2028.
- **Research and Development Expenses** were $14.5 million for the three months ended September 30, 2026, compared to $13.4 million for the same period in 2025.
- **General and Administrative Expenses** were $5.9 million for the three months ended September 30, 2026, compared to $5.2 million for the same period in 2025.
- **Net Loss** was $19.4 million, or $(0.28) basic and diluted net loss per share, for the three months ended September 30, 2026, compared to $18.0 million, or $(0.52) basic and diluted net loss per share, for the same period in 2025. PepGen had approximately 69.3 million shares outstanding on September 30, 2026.

About Myotonic Dystrophy Type 1 (DM1)
Myotonic dystrophy type 1 (DM1) is a rare, progressive genetic disease that affects muscles and multiple systems throughout the body. DM1 is caused by an abnormal expansion of cytosine-thymine-guanine (CTG) repeats in the *dystrophia myotonica protein kinase* (*DMPK*) gene, resulting in pathogenic RNA that interferes with normal RNA splicing and drives the disease. Symptoms can begin in childhood or adulthood and vary widely in type, severity, and progression. DM1 has a world-wide distribution and is estimated to affect more than 110,000 people across the United States and the European Union, and average life expectancy for people with non-congenital DM1 is approximately 50 to 60 years. No approved therapies currently address the underlying cause of DM1.

About PGN-EDODM1
PGN-EDODM1 is an investigational Enhanced Delivery Oligonucleotide (EDO) designed to address the underlying molecular mechanism of DM1. Using PepGen's proprietary EDO technology designed to enhance cellular uptake and nuclear delivery of a therapeutic oligonucleotide, PGN-EDODM1 selectively binds to expanded CUG repeats in pathogenic *dystrophia myotonica protein kinase* (*DMPK*) RNA. This binding releases MBNL1, a key regulator of RNA splicing, to restore correct splicing. Unlike approaches that degrade *DMPK* RNA, PGN-EDODM1 is designed to disrupt pathogenic *DMPK* hairpin structures while preserving normal *DMPK* function. The U.S. Food and Drug Administration has granted PGN-EDODM1 Orphan Drug and Fast Track designations, and the European Medicines Agency has granted it Orphan Designation.

About FREEDOM2-DM1
FREEDOM2-DM1 (NCT06667453) is a multinational, randomized, double-blind, placebo-controlled Phase 2 multiple ascending dose study evaluating PGN-EDODM1 in people living with DM1. The study enrolled three cohorts of eight participants each, randomized 3:1 to receive PGN-EDODM1 or placebo at doses of 5, 10, or 12.5 mg/kg. Participants receive four intravenous doses every four weeks over 12 weeks. Key endpoints include safety and tolerability, pharmacokinetics, correction of RNA mis-splicing in muscle tissue, and functional measures of myotonia, strength, and mobility. FREEDOM2 is being conducted in Canada, the United Kingdom, New Zealand, Australia, and South Korea and is subject to a partial clinical hold in the United States. Eligible participants may continue treatment in the FREEDOM-OLE study.

About PepGen
PepGen Inc. is a clinical-stage biotechnology company pioneering oligonucleotide therapies with the potential to transform the treatment of rare genetic diseases. Founded on more than a decade of research and development, PepGen's Enhanced Delivery Oligonucleotide (EDO) technology leverages cell-penetrating peptides to improve the uptake and activity of conjugated oligonucleotide therapeutics. Using this EDO technology, PepGen is advancing PGN-EDODM1, a clinical candidate for the treatment of myotonic dystrophy type 1.

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, statements regarding PGN-EDODM1's potential to deliver meaningful benefit to the DM1 community, expectations regarding the timing of data for the 12.5 mg/kg cohort of the FREEDOM2-DM1 trial, the FREEDOM-OLE 10 mg/kg safety and 5 mg/kg clinical results, our plans to initiate an expansion cohort running in parallel to cohort 3, timing regarding the end-of-Phase 2 (EOP2) meeting for FREEDOM2 and FREEDOM-OLE studies, the potential for the CDRP program to accelerate alignment on critical manufacturing development strategies ahead of Phase 3 and NDA submission, forecasts relating to PepGen's cash runway, 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 or cross-trial comparisons, including for PGN-EDODM1 and cross-trial comparisons; 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 or approval by regulatory authorities with respect to our programs, including clearance to commence planned clinical studies of our product candidates including the lifting of the partial clinical hold on PGN-EDODM1, or other regulatory feedback requiring modifications to our development programs, including in each case with respect to our PGN-EDODM1 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 approval from regulatory authorities.

Condensed Consolidated Statements of Operations
(unaudited, in thousands)

	Three Months Ended September 30,	
	2026	**2025**
Operating expenses:		
Research and development	$ 14,476	$ 13,423
General and administrative	5,907	5,231
Total operating expenses	$ 20,383	$ 18,654
Operating loss	$ (20,383)	$ (18,654)
Other income (expense)		
Interest income	1,005	634
Other (expense) income, net	—	(6)
Total other income, net	1,005	628
Net loss before income tax	$ (19,378)	$ (18,026)
Income tax expense	(13)	—
Net loss	$ (19,391)	$ (18,026)
Net loss per share, basic and diluted	$ (0.28)	$ (0.52)
Weighted-average common stock outstanding, basic and diluted	69,260,353	34,362,876

Condensed Consolidated Balance Sheets
(unaudited, in thousands)

	September 30, 2026	**December 31, 2025**
Assets		
Cash, cash equivalents and marketable securities	$ 104,805	$ 148,456
Other assets	22,972	25,451
Total assets	$ 127,777	$ 173,907
Liabilities and stockholders' equity		
Liabilities	$ 24,711	$ 26,463

Stockholders' equity	103,066	147,444
Total liabilities and stockholders' equity	$ 127,777	$ 173,907

View source version on businesswire.com: https://www.businesswire.com/news/home/20261110685903/en/

Investor Contact
Laurence Watts
New Street Investor Relations
laurence@newstreetir.com

Media Contact
Amir Khan
Chamberlain Healthcare PR
Amir.Khan@syneoshealth.com

Source: PepGen Inc.