PepGen Reports Third Quarter 2024 Financial Results and Recent Corporate Highlights

November 7, 2024

– FREEDOM-DM1 data from 5 and 10 mg/kg cohorts in patients with DM1 expected in the first quarter of 2025 –

– Study designs of CONNECT program optimized based on encouraging results from early cohort –

– Strengthened leadership team with addition of Paul Streck, MD, MBA, as head of R&D –

BOSTON--(BUSINESS WIRE)--Nov. 7, 2024-- 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 and recent corporate highlights for the quarter ended September 30, 2024.

"We are pleased with the progress we have made across our pipeline and organization during the third quarter, as we continued to advance our lead clinical programs and strengthened our leadership team with the addition of Paul Streck to head our research and clinical development efforts. Paul has already made a positive impact on our organization and our clinical development strategy in both myotonic dystrophy type 1 (DM1) and Duchenne muscular dystrophy (DMD)," said James McArthur, PhD, President and CEO of PepGen. Said Paul Streck, MD, MBA, Head of R&D: "In our DM1 program, the 10 mg/kg cohort of our FREEDOM-DM1 study is fully enrolled and we are encouraged by the emerging data from both the 5 and 10 mg/kg cohorts. We look forward to presenting a fulsome update of both cohorts by the end of the first quarter of 2025, followed by additional data readouts expected from the DM1 and DMD programs during 2025."

Continued Dr. McArthur: "We leveraged the encouraging 5 mg/kg results from our CONNECT1-EDO51 study in DMD reported in July to further optimize the study designs of both CONNECT1 and CONNECT2-EDO51. With these protocol enhancements in place, we expect to report data from the expanded CONNECT1 10 mg/kg cohort before year-end 2025. We remain deeply committed to advancing our programs with the goal of improving the lives of individuals suffering from severe neuromuscular and neurological diseases."

Recent Program Updates

PGN-EDODM1: Myotonic Dystrophy Type 1

- **Phase 1 FREEDOM-DM1 Clinical Trial of PGN-EDODM1**: The FREEDOM Phase 1 single ascending dose (SAD) study continues, and the Company expects to report safety, splicing correction and functional outcome measures from both the 5 mg/kg and 10 mg/kg dose cohorts by the end of the first quarter of 2025. The FREEDOM study is evaluating PGN-EDODM1 in approximately 32 adult patients with DM1 in the United States, Canada, and the United Kingdom. The Company expects to report results from the 15 mg/kg cohort in the second half of 2025.

- **Phase 2 FREEDOM2-DM1 Clinical Trial of PGN-EDODM1**: FREEDOM2 is a Phase 2 randomized, double-blind, placebo-controlled, multiple ascending dose (MAD) clinical trial evaluating PGN-EDODM1 in approximately 24 adult patients with DM1 in Canada, the United Kingdom, and, subject to regulatory clearance, the United States. The Company expects to initiate dosing in FREEDOM2 by year-end.

PGN-EDO51: Duchenne Muscular Dystrophy

- **Phase 2 CONNECT1-EDO51 Clinical Trial of PGN-EDO51**: Following encouraging data from the 5 mg/kg cohort reported in July, the Company continues to advance the CONNECT1 study. Based on learnings from the 5 mg/kg cohort, PepGen has amended the CONNECT1 study protocol. The changes include adjusting the timing for the final biopsy from Day 7 to Day 28 following the last dose of PGN-EDO51, adjusting the Performance of Upper Limb (PUL) test entry score from 3 to 4 for inclusion, and adjusting the eligible age group from 8 years of age and older to 6-16 years of age, all subject to regulatory clearance. The Company has also expanded the 10 mg/kg cohort from 3 to 4 participants. With these adjustments, the Company now expects to report results from the 10 mg/kg cohort by year-end 2025.

- **Phase 2 CONNECT2-EDO51 Clinical Trial of PGN-EDO51**: Based on the data from

CONNECT1, including the favorable emerging safety profile of PGN-EDO51, the Company is also working to optimize the design of the multinational CONNECT2 Phase 2 double-blind, placebo-controlled, MAD, 25-week trial. The CONNECT2 clinical trial is open in the United Kingdom. The Company continues to engage with regulators in the European Union and expects to open the clinical trial in the United States by year-end, subject to regulatory clearance.

Corporate Update

- In August, PepGen appointed Paul Streck, MD, MBA, as Executive Vice President and Head of the Company's R&D organization. He brings more than 20 years of leadership experience in drug development, regulatory, and medical affairs.
- In September and October, the Company presented scientific and clinical data at numerous medical conferences, including at the 29th Annual Congress of the World Muscle Society. All of the presentations are available on the Investors page of PepGen's website under Scientific Publications.

Financial Results for the Three Months Ended September 30, 2024

- **Cash, Cash Equivalents and Marketable Securities** were $138.9 million as of September 30, 2024, which is anticipated to fund currently planned operations into 2026.
- **Research and Development Expenses** were $17.7 million for the three months ended September 30, 2024, compared to $20.5 million for the same period in 2023.
- **General and Administrative Expenses** were $5.4 million for the three months ended September 30, 2024, compared to $4.2 million for the same period in 2023.
- **Net Loss** was $21.4 million, or $(0.66) basic and diluted net loss per share, for the three months ended September 30, 2024, compared to $23.3 million, or $(0.98) basic and diluted net loss per share, for the same period in 2023. PepGen had approximately 32.6 million shares outstanding on September 30, 2024.

About PGN-EDODM1

PGN-EDODM1, PepGen's investigational candidate in development for the treatment of DM1, utilizes the Company's proprietary Enhanced Delivery Oligonucleotide (EDO) technology to deliver a therapeutic oligonucleotide that is designed to restore the normal splicing function of MBNL1, a key RNA splicing protein. DM1 is a progressively disabling, life-shortening genetic disorder. DM1 is estimated to affect 40,000 people in the United States, and over 74,000 people in Europe. 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.

About PGN-EDO51

PGN-EDO51, PepGen's clinical candidate for the treatment of DMD, utilizes the Company's proprietary EDO technology to deliver a therapeutic phosphorodiamidate morpholino oligomer (PMO) that is designed to target the root cause of this devastating disease. PGN-EDO51 is designed to skip exon 51 of the dystrophin transcript, an established therapeutic target for approximately 13% of DMD patients, thereby aiming to restore the open reading frame and enabling the production of a truncated, yet functional dystrophin protein. The U.S. Food and Drug Administration has granted PGN-EDO51 both Orphan Drug and Rare Pediatric Disease Designations for the treatment of patients with DMD amenable to an exon-51 skipping approach.

About PepGen

PepGen is 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. PepGen's 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, we are 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 our product candidates, including, based on early data, PGN-EDO51 and PGN-EDODM1, the design, initiation and conduct of clinical trials, including expected timelines for our CONNECT1 and CONNECT2 Phase 2 trials, our FREEDOM Phase 1 trial and our FREEDOM2 Phase 2 trial, the expected timing for

additional data reports from our CONNECT1 Phase 2 trial, and our FREEDOM Phase 1 trial, ongoing and planned regulatory interactions, and our financial resources and expected cash runway.

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-EDO51 and PGN-EDODM1; our ability to enroll patients in our clinical trials, including CONNECT1, CONNECT2, FREEDOM and 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-EDO51 and PGN-EDODM1; our product candidates, including PGN-EDO51 and 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, or other regulatory feedback requiring modifications to our development programs, including in each case with respect to our CONNECT1, CONNECT2, FREEDOM and FREEDOM2 clinical trials; 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 annual report on Form 10-K and quarterly report on Form 10-Q that are 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-EDO51 and PGN-EDODM1, investigational therapies that have not been approved for use in any country and is not intended to convey conclusions about their efficacy or safety. There is no guarantee that PGN-EDO51, PGN-EDODM1 or any other investigational therapy will successfully complete clinical development or gain regulatory authority approval.

Condensed Consolidated Statements of Operations
(unaudited, in thousands)

	Three Months Ended September 30,	
	2024	**2023**
Operating expenses:		
Research and development	$ 17,722	$ 20,540
General and administrative	5,449	4,240
Total operating expenses	$ 23,171	$ 24,780
Operating loss	$ (23,171)	$ (24,780)
Other income (expense)		
Interest income	1,826	1,578
Other (expense) income, net	(39)	(88)
Total other income, net	1,787	1,490
Net loss before income tax	$ (21,384)	$ (23,290)
Income tax expense	—	—
Net loss	$ (21,384)	$ (23,290)
Net loss per share, basic and diluted	$ (0.66)	$ (0.98)
Weighted-average common shares outstanding, basic and diluted	32,581,542	23,790,430

Condensed Consolidated Balance Sheets
(unaudited, in thousands)

	September 30, 2024	December 31, 2023
Assets		
Cash, cash equivalents and marketable securities	$ 138,857	$ 110,407
Other assets	31,377	32,645
Total assets	$ 170,234	$ 143,052
Liabilities and stockholders' equity		
Liabilities	$ 32,779	$ 34,631
Stockholders' equity	137,455	108,421
Total liabilities and stockholders' equity	$ 170,234	$ 143,052

View source version on businesswire.com: https://www.businesswire.com/news/home/20241107757419/en/

Investor Contact
Dave Borah, CFA
SVP, Investor Relations and Corporate Communications
dborah@pepgen.com

Media Contact
Julia Deutsch

Lyra Strategic Advisory
Jdeutsch@lyraadvisory.com

Source: PepGen Inc.