PepGen Reports Second Quarter 2024 Financial Results and Recent Corporate Highlights

August 8, 2024

– CONNECT1-EDO51 clinical trial data from low-dose cohort were reported in July. PGN-EDO51 at 5 mg/kg was well tolerated, achieved mean exon skipping levels of 2.15%, mean muscle-adjusted dystrophin production increase of 0.70% from baseline and mean absolute dystrophin production increase of 0.26% from baseline, after three months of dosing –

– FREEDOM2-DM1 clinical trial cleared by Health Canada and U.K. Medicines and Healthcare products Regulatory Agency. Initial dosing expected second half of 2024 –

– FREEDOM-DM1 clinical results update expected in fourth quarter of 2024 –

BOSTON--(BUSINESS WIRE)--Aug. 8, 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 June 30, 2024.

“Our July readout of the CONNECT1 5 mg/kg clinical data in Duchenne muscular dystrophy (DMD) was the culmination of years of dedicated effort from our team,” said James McArthur, Ph.D., President and CEO of PepGen. “In three months, PGN-EDO51 produced higher mean levels of exon skipped transcript at lower doses and in a shorter period than other exon 51 therapies, approved or in development. We believe this indicates our Enhanced Delivery Oligonucleotide (EDO) technology is delivering greater levels of oligonucleotide to the nuclei. We are also very pleased PGN-EDO51 was well tolerated and that all patients experienced increases in dystrophin production. We look forward to our upcoming FREEDOM-DM1 clinical results update as we believe our EDO platform has the potential to dramatically improve the lives of people living with severe neuromuscular and neurological diseases.”

Recent Program Highlights

PGN-EDO51: Duchenne Muscular Dystrophy (DMD)

Phase 2 CONNECT1-EDO51 Clinical Trial of PGN-EDO51: In July 2024, PepGen reported clinical data from the 5 mg/kg PGN-EDO51 dose cohort, including initial safety, exon 51 skipping, and dystrophin production data. CONNECT1 is a Phase 2, open-label, multiple ascending dose (MAD) clinical trial, being conducted in Canada, evaluating PGN-EDO51 in approximately 10 male patients at least 8 years of age with DMD amenable to an exon 51-skipping approach.

- **At the 5 mg/kg Dose**
  - PGN-EDO51 was well tolerated by all study cohort participants through week 13. There were no discontinuations, dose interruptions or dose reductions.
  - PGN-EDO51 produced mean exon skipping in biceps tissue of 2.15% at week 13 compared to baseline.
  - PGN-EDO51 achieved a mean muscle-adjusted dystrophin level of 1.49% of normal and a 0.70% increase from baseline after 4 doses, measured at week 13.
  - PGN-EDO51 achieved a mean absolute dystrophin level of 0.61% of normal and a 0.26% increase from baseline after 4 doses, measured at week 13 by Western blot analysis.
- The Company plans to present additional results from the 5 mg/kg cohort at a medical meeting later in the year.
- The Company expects to report initial results from the 10 mg/kg cohort of CONNECT1-EDO51 in early 2025.

Phase 2 CONNECT2-EDO51 Clinical Trial of PGN-EDO51: Based on the data from CONNECT1, including PGN-EDO51’s emerging safety profile to date, the Company is 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.

PGN-EDODM1: Myotonic Dystrophy 1 (DM1)

- **Phase 1 FREEDOM-DM1 Clinical Trial of PGN-EDODM1**: PepGen anticipates reporting clinical results from the FREEDOM clinical trial, including safety, splicing correction, and functional outcome measures, in the fourth quarter of 2024. FREEDOM is a Phase 1 single ascending dose clinical trial evaluating PGN-EDODM1 in approximately 24 adult patients with

DM1 in the United States, Canada, and the United Kingdom.

- **Phase 2 FREEDOM2-DM1 Clinical Trial of PGN-EDODM1**: PepGen is announcing today that both Health Canada and the United Kingdom Medicines and Healthcare products Regulatory Agency have cleared the Company's clinical trial application (CTA) submissions for the FREEDOM2 trial, and PepGen expects to initiate patient dosing in the second half of 2024. FREEDOM2 is a Phase 2 randomized, double-blind, placebo-controlled, MAD clinical trial evaluating PGN-EDODM1 in approximately 24 adult patients with DM1 in Canada, the United Kingdom, and in the United States, subject to regulatory clearance.
- **PGN-EDODM1 Poster:** In April 2024, PepGen presented a poster on the PGN-EDODM1 program at the 14th International Myotonic Dystrophy Consortium (2024 IDMC-14) Meeting.
    - Poster title: FREEDOM-DM1: Phase 1 Study Design to Assess Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of PGN-EDODM1 for Myotonic Dystrophy Type 1.

The PGN-EDODM1 poster presented at the 2024 IDMC-14 Meeting is available on the Investors page of PepGen's website under Scientific Publications.

PGN-EDO53 (DMD)

- **PepGen continues to advance PGN-EDO53** in investigational new drug (IND) and CTA enabling nonclinical studies.

Financial Results for the Three Months Ended June 30, 2024

- **Cash, cash equivalents and marketable securities** were $161.3 million as of June 30, 2024, which is anticipated to fund currently planned operations into 2026.
- **Research and Development expenses** were $25.1 million for the three months ended June 30, 2024, compared to $16.9 million for the same period in 2023.
- **General and Administrative expenses** were $5.4 million for the three months ended June 30, 2024, compared to $4.2 million for the same period in 2023.
- **Net loss** was $28.3 million, or $(0.87) basic and diluted net loss per share, for the three months ended June 30, 2024, compared to $19.5 million, or $(0.82) basic and diluted net loss per share, for the same period in 2023. PepGen had approximately 32.6 million shares outstanding on June 30, 2024.

About PGN-EDO51

PGN-EDO51, PepGen's lead clinical candidate for the treatment of Duchenne muscular dystrophy (DMD), utilizes the Company's proprietary Enhanced Delivery Oligonucleotide (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 PGN-EDODM1

PGN-EDODM1, PepGen's second 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. 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 PepGen

PepGen Inc. 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, PGN-EDODM1 and, based on early data, PGN-EDO51, the potential of our EDO platform to deliver higher levels of oligonucleotide to the nuclei and to dramatically improve the lives of people living with severe neuromuscular and neurological diseases, the design, initiation and conduct of clinical trials, including expected timelines for our CONNECT2 Phase 2 trial and FREEDOM2 Phase 2 trial, the expected timing for additional results from our CONNECT1 Phase 2 trial and results from our FREEDOM Phase 1 trial, ongoing and planned regulatory interactions, the advancement of PGN-EDO53 in IND/CTA enabling studies, and our financial resources and 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, PGN-EDODM1 and PGN-EDO53; 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, 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-EDO51 or any other investigational therapy will successfully complete clinical development or gain regulatory authority approval.

Consolidated Statements of Operations
(unaudited, in thousands)

	Three Months Ended June 30,	
	2024	**2023**
Operating expenses:		
Research and development	$ 25,063	$ 16,926
General and administrative	5,362	4,218
Total operating expenses	$ 30,425	$ 21,144
Operating loss	$ (30,425)	$ (21,114)
Other income (expense)		
Interest income	2,121	1,684
Other income, net	(31)	(62)
Total other income (expense), net	2,090	1,622
Net loss before income tax	$ (28,335)	$ (19,522)
Income tax expense	—	—
Net loss	$ (28,335)	$ (19,522)
Net loss per share, basic and diluted	$ (0.87)	$ (0.82)
Weighted-average common shares outstanding, basic and diluted	32,469,187	23,790,430

Condensed Consolidated Balance Sheets
(unaudited, in thousands)

	June 30, 2024	December 31, 2023
Assets		
Cash, cash equivalents and marketable securities	$ 161,306	$ 110,407
Other assets	32,204	32,645
Total assets	$ 193,510	$ 143,052
Liabilities and stockholders’ equity		
Liabilities	$ 38,470	$ 34,631
Stockholders’ equity:	155,040	108,421
Total liabilities and stockholders’ equity	$ 193,510	$ 143,052

View source version on businesswire.com: https://www.businesswire.com/news/home/20240808826731/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.