PepGen Reports First Quarter 2024 Financial Results and Recent Corporate Highlights

May 14, 2024

– CONNECT1-EDO51 trial preliminary data from 5mg/kg dose cohort expected mid-2024 –

– FREEDOM1-DM1 trial preliminary data from at least 5mg/kg dose cohort expected second half 2024 –

– Net proceeds of $86.3 million from common stock offerings extending cash runway into 2026 –

BOSTON, May 14, 2024 (GLOBE NEWSWIRE) -- 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 March 31, 2024.

“Our team has made exceptional progress in the first quarter advancing multiple clinical trials for Duchenne muscular dystrophy (DMD) and myotonic dystrophy type 1 (DM1),” said James McArthur, Ph.D., President and CEO of PepGen. “We are on track to achieve several significant milestones during the remainder of 2024, including sharing preliminary data from both the CONNECT1-EDO51 and FREEDOM-DM1 clinical trials and initiating the FREEDOM2-DM1 Phase 2 clinical trial in people living with DM1.”

Recent Program Highlights

PGN-EDO51: Duchenne Muscular Dystrophy (DMD)

PGN-EDO51, PepGen's lead investigational candidate in development for the treatment of DMD, utilizes the Company's proprietary Enhanced Delivery Oligonucleotide (EDO) technology to deliver a therapeutic oligonucleotide 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.

- **Phase 2 CONNECT1-EDO51 Clinical Trial of PGN-EDO51**: In March 2024, PepGen announced that the 5 mg/kg PGN-EDO51 dose cohort was fully enrolled. PepGen expects to report preliminary data from this cohort in mid-2024, including initial safety, exon 51 skipping, and dystrophin production data. CONNECT1-EDO51 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.
- **Phase 2 CONNECT2-EDO51 Clinical Trial of PGN-EDO51**: In March 2024, PepGen announced that it had received authorization from the Medicines and Healthcare products Regulatory Agency (MHRA) to initiate CONNECT2-EDO51 in the United Kingdom. CONNECT2 is a Phase 2, randomized, double-blind, placebo-controlled MAD clinical trial, evaluating PGN-EDO51 in approximately 20 male patients at least 6 years of age with DMD amenable to an exon 51-skipping approach. PepGen plans to extend this study to the United States and other countries, subject to regulatory authorizations. The CONNECT2 clinical trial, together with the data from CONNECT1, is designed to potentially support a future accelerated approval pathway, subject to regulatory authority feedback.
- **Orphan Drug and Rare Pediatric Disease Designations granted to PGN-EDO51**: In March 2024, PepGen announced that the U.S. Food and Drug Administration has granted both Orphan Drug and Rare Pediatric Disease Designations for PGN-EDO51 for the treatment of patients with DMD amenable to an exon-51 skipping approach.
- In March 2024, PepGen presented two posters on the PGN-EDO51 program at the 2024 Muscular Dystrophy Association (MDA) Clinical & Scientific Conference.
    - Poster title: Single- and Repeat-Dose Nonclinical Data for PGN-EDO51 Demonstrated Potential for the Treatment of DMD.
    - Poster title: CONNECT1-EDO51 and CONNECT2-EDO51: Phase 2 Study Designs to

Evaluate Safety and Efficacy for DMD Amenable to Exon 51 Skipping.

PGN-EDODM1: Myotonic Dystrophy 1 (DM1)

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 U.S., and over 74,000 people in Europe.

- **Phase 1 FREEDOM-DM1 Clinical Trial of PGN-EDODM1**: PepGen anticipates reporting preliminary data from at least the 5 mg/kg PGN-EDODM1 dose cohort, including safety, splicing correction, and functional outcome measures, in the second half of 2024. FREEDOM-DM1 is a Phase 1 single ascending dose (SAD) clinical trial evaluating PGN-EDODM1 in approximately 24 adult patients with DM1 in the U.S., Canada, and the United Kingdom.
- 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.
- In March 2024, PepGen presented two posters on the PGN-EDODM1 program at the 2024 MDA Clinical & Scientific Conference.
    - Poster title: PGN-EDODM1 Single- and Repeat-Dose Nonclinical Data Indicated Mechanistic and Meaningful Activity for Potential Treatment of DM1.
    - Poster title: FREEDOM-DM1: Phase 1 Study Design to Assess Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of PGN-EDODM1 for DM1.

PGN-EDO51 and PGN-EDODM1 posters presented at the 2024 MDA Conference, and PGN-EDODM1 poster presented at the 2024 IDMC-14 Meeting, are available on the Investors page of our website under past events within the Events & Presentations page of the News & Events section.

PGN-EDO53: DMD

PGN-EDO53, PepGen's third investigational candidate for the treatment of DMD, utilizes the Company's proprietary EDO technology to deliver a therapeutic oligonucleotide that is designed to target the root cause of this devastating disease. PGN-EDO53 is designed to skip exon 53 of the dystrophin transcript, an established therapeutic target for approximately 8% of DMD patients.

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

Other Corporate Updates

- In February 2024, PepGen received $9.9 million from its at-the-market offering program and $76.4 million from an underwritten public offering, resulting in net proceeds of $86.3 million.

Financial Results for the Three Months Ended March 31, 2024

- **Cash, cash equivalents and marketable securities** were $175.2 million as of March 31, 2024, inclusive of net proceeds from the recent common stock offerings, which is anticipated to fund currently planned operations into 2026.
- **Research and Development expenses** were $14.7 million for the three months ended March 31, 2024, compared to $14.4 million for the same period in 2023.
- **General and Administrative expenses** were $5.1 million for the three months ended March 31, 2024, compared to $3.7 million for the same period in 2023.

- **Net loss** was $18.0 million for the three months ended March 31, 2024, compared to $16.3 million for the same period in 2023. PepGen had approximately 32.4 million shares outstanding on March 31, 2024.

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 Enhanced Delivery Oligonucleotide, or 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 that are designed to target the root cause of serious diseases.

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-EDO51 and PGN-EDODM1, our technology, including our EDO platform, the design, initiation and conduct of clinical trials, including expected timelines for our CONNECT2-EDO51 Phase 2 trial and FREEDOM2-DM1 Phase 2 trial and preliminary data reports from our CONNECT1-EDO51 Phase 2 trial and FREEDOM-DM1 Phase 1 trial, the advancement of PGN-EDO53 into IND/CTA enabling studies, regulatory interactions, including development pathway for our product candidates, 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-EDO51, CONNECT2-EDO51 and FREEDOM-DM1; 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; 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-EDO51, CONNECT2-EDO51, FREEDOM-DM1 and FREEDOM2-DM1 programs; 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.

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Condensed Consolidated Statements of Operations
(unaudited, in thousands)

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$ 14,732	$ 14,360
General and administrative	5,066	3,671
Total operating expenses	$ 19,798	$ 18,031
Operating loss	$ (19,798)	$ (18,031)
Other income (expense)		
Interest income	1,735	1,792
Other income, net	43	(80)
Total other income (expense), net	1,778	1,712
Net loss before income tax	$ (18,020)	$ (16,319)
Income tax expense	—	—
Net loss	$ (18,020)	$ (16,319)

Condensed Consolidated Balance Sheets
(unaudited, in thousands)

	March 31, 2024	December 31, 2023
Assets		
Cash, cash equivalents and marketable securities	$ 175,223	$ 110,407
Other assets	31,777	32,645
Total assets	$ 207,000	$ 143,052
Liabilities and stockholders' equity		
Liabilities	$ 28,001	$ 34,631
Stockholders' equity:	178,999	108,421
Total liabilities and stockholders' equity	$ 207,000	$ 143,052