PepGen Reports Fourth Quarter and Full Year 2023 Financial Results and Recent Corporate Developments

March 6, 2024

- Enrollment completed for PGN-EDO51 5 mg/kg cohort in CONNECT1-EDO51 Phase 2 clinical trial in DMD patients. The Company expects to announce preliminary data from the 5 mg/kg dose cohort in mid-2024 –

- CONNECT2-EDO51 Phase 2 clinical trial in DMD patients open in the U.K. - Company believes this study could potentially support accelerated approval -

- FREEDOM-DM1 Phase 1 clinical trial enrolling DM1 patients with preliminary data for at least the 5 mg/kg dose cohort expected in the second half of 2024 -

- Gross proceeds of approximately $80 million from February 2024 follow-on offering extends projected operating cash runway into 2026 -

BOSTON, March 06, 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 for the fourth quarter and full year ended December 31, 2023, and highlighted recent corporate developments.

"With important data readouts expected from our two lead programs, 2024 has the potential to be a transformational year for PepGen. In the last year, PepGen made meaningful advancements with our Enhanced Delivery Oligonucleotide (EDO) therapeutic candidates, including the initiation and dosing of patients in both our CONNECT1-EDO51 Phase 2 and FREEDOM-DM1 Phase 1 clinical trials," said James McArthur, Ph.D., President and CEO of PepGen. "Following the recent completion of enrollment of cohort 1 of our CONNECT1-EDO51 trial, we look forward to sharing preliminary safety, exon 51 skipping, and dystrophin production data from the 5 mg/kg dose in mid-2024."

Dr. McArthur continued, "We continue to see encouraging enrollment in our ongoing FREEDOM-DM1 Phase 1 clinical trial. People with myotonic dystrophy type 1 (DM1) currently have no approved treatment options that target the root cause of the disease. We believe that PGN-EDODM1 has the potential to be disease-modifying and could generate meaningful, double-digit levels of splicing correction and corresponding correction of functional measures. We look forward to reporting preliminary data from at least the 5 mg/kg dose cohort later this year."

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 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 people with DMD.

- **Phase 2 CONNECT1-EDO51 Clinical Trial of PGN-EDO51 underway and 5 mg/kg cohort fully enrolled:** In January 2024, PepGen announced that the first patient had been dosed in its Phase 2, open-label multiple ascending dose (MAD) CONNECT1-EDO51 clinical trial, being conducted in Canada, evaluating PGN-EDO51 in 10 male patients at least 8 years of age with DMD amenable to an exon 51-skipping approach. The starting dose will escalate from 5 mg/kg to 10 mg/kg with a potential for further dose escalations. All dose escalations will be determined based on evaluation of safety data from the prior dose cohort(s).
    - PepGen is announcing that the 5 mg/kg PGN-EDO51 dose cohort is fully enrolled. PepGen expects to report preliminary data from this cohort in mid-2024, including initial safety, exon 51 skipping, and dystrophin production data.
- **Initiation of 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 its Phase 2, randomized, double-blind, placebo-controlled MAD CONNECT2-EDO51 clinical trial in the United Kingdom 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 CONNECT 2-EDO51 clinical trial, together with the data from CONNECT1-EDO51, is designed to potentially support a future accelerated approval pathway, subject to alignment with regulatory authorities.

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. 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.

- **Fast Track Designation granted to PGN-EDODM1:** In February 2024, PepGen announced that the U.S. Food and Drug Administration granted Fast Track Designation to PGN-EDODM1 for the treatment of DM1.

- **First Patient Dosed in Phase 1 FREEDOM-DM1 Clinical Trial of PGN-EDODM1:** In December 2023, PepGen announced that the first patient had been dosed in its Phase 1 single ascending dose (SAD) FREEDOM-DM1 clinical trial evaluating PGN-EDODM1 in 24 adult patients with DM1 in the U.S., Canada, and the United Kingdom. The starting dose of 5 mg/kg can escalate to 10 mg/kg, and then 20 mg/kg based on evaluation of safety data from the prior dose cohort(s).
    - 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.

In addition to the ongoing FREEDOM-DM1 trial, PepGen expects to open its FREEDOM2-DM1 placebo controlled, MAD clinical trial in DM1 patients in the second half of 2024.

Preclinical PGN-EDO53: DMD

PGN-EDO53 is PepGen's third investigational candidate for the treatment of DMD that 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 people with DMD.

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

Additional Corporate Highlights

$80 Million Underwritten Offering of Common Stock: In February 2024, PepGen priced an underwritten offering of 7,530,000 shares of common stock at a price to the public of $10.635 per share, for aggregate gross proceeds to PepGen of approximately $80 million, before deducting commissions and expenses payable by PepGen.

Financial Results for the Three Months and Twelve Months ended December 31, 2023

- **Cash and cash equivalents** were $110.4 million as of December 31, 2023. Based on the Company's current operating plan and projections, it believes that current cash, cash equivalents and marketable securities, together with the net proceeds from its recent common stock offering, will be sufficient to fund projected operating requirements into 2026.

- **Research and development expenses** were $16.3 million for the three months ended December 31, 2023, compared to $13.2 million for the same period in 2022. Research and development expenses were $68.1 million for the year ended December 31, 2023, compared to $54.1 million for the same period in 2022. The increase in research and development expenses was primarily due to costs associated with the advancement of the Company's PGN-EDO51 and PGN-EDODM1 programs, including preclinical, clinical, and manufacturing costs for our ongoing and future clinical trials.

- **General and administrative expenses** were $4.5 million for the three months ended December 31, 2023, compared to $4.0 million for the same period in 2022. General and administrative expenses were $16.6 million for the year ended December 31, 2023, compared to $14.2 million for the same period in 2022. The increase in general and administrative expenses was primarily due to increased personnel-related costs.

- **Net loss** was $19.5 million for the three months ended December 31, 2023, compared to

$14.9 million for the same period in 2022. Net loss was $78.6 million for the year ended December 31, 2023, compared to $69.1 million for the same period in 2022. PepGen had approximately 23.8 million shares outstanding on December 31, 2023.

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, PGN-EDODM1 and PGN-EDO53, our technology, including our EDO platform, the design, initiation and conduct of clinical trials, including expected timelines, dose levels and dose escalation, including for our CONNECT2-EDO51 Phase 2 trial and our FREEDOM2-DMI trial, as well as 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 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, PGN-EDODM1 and PGN-EDO53; our ability to enroll patients in our clinical trials, including CONNECT1-EDO51, CONNECT2-EDO51, FREEDOM-DM1and FREEDOM2-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, including CONNECT2-EDO51, or other regulatory feedback requiring modifications to our development programs; changes in regulatory framework that are out of our control; our ability to obtain, maintain and protect our intellectual property; our ability to enforce our patents against infringers and defend our patent portfolio against challenges from third parties; competition from others developing therapies for the indications we are pursuing; 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.

PepGen Inc.
Condensed Statement of Operations
(in thousands, unaudited)

	Twelve Months Ended December 31,		Three Months Ended December 31,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 68,126	$ 54,077	$ 16,300	$ 13,166
General and administrative	16,640	14,224	4,511	4,047
Total operating expenses	$ 84,766	$ 68,301	$ 20,811	$ 17,213
Operating loss	$ (84,766)	$ (68,301)	$ (20,811)	$ (17,213)
Other income (expense)				
Interest income	6,400	2,793	1,346	1,591
Other income (expense), net	(187)	110	43	(28)
Total other income, net	6,213	2,903	1,389	1,563
Net loss before income tax	$ (78,553)	$ (65,398)	$ (19,422)	$ (15,650)
Income tax (expense) benefit	(73)	(3,706)	(73)	714
Net loss	$ (78,626)	$ (69,104)	$ (19,495)	$ (14,936)

PepGen Inc.
Condensed Balance Sheet Data
(in thousands, unaudited)

	December 31,	
	2023	**2022**
Assets		
Cash, cash equivalents and marketable securities	$ 110,407	$ 181,752
Other assets	32,645	35,688

Total assets	$ 143,052	$ 217,440
Liabilities and stockholders' equity		
Liabilities	$ 34,631	$ 37,809
Stockholders' equity:	108,421	179,631
Total liabilities and stockholders' equity	$ 143,052	$ 217,440

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