PepGen Reports Second Quarter 2023 Financial Results and Recent Corporate Developments

August 8, 2023

– Phase 2 open-label CONNECT1-EDO51 study open in Canada –

– Potentially registrational, randomized, double-blind, placebo-controlled Phase 2 CONNECT2-EDO51 multinational study expected to be initiated in the second half of 2023 –

– Continue to pursue global strategy of initiating FREEDOM-EDODM1 clinical study in geographies outside the U.S. –

– Continue to work closely with FDA to lift the clinical hold and initiate the Phase 1 FREEDOM-EDODM1 study in the U.S. as quickly as feasible –

– Ended second quarter 2023 with cash and cash equivalents of $147.0 million; cash runway expected into 2025 –

BOSTON, Aug. 08, 2023 (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 second quarter ended June 30, 2023 and highlighted recent corporate developments.

“PepGen continues to make strong progress across our pipeline of clinical and pre-clinical stage conjugated oligonucleotide therapies for neuromuscular and neurological diseases," said James McArthur, Ph.D., President and CEO of PepGen. “We continue to expect to report, from the CONNECT1 study, initial dystrophin production, exon skipping and safety data following 4 monthly doses of PGN-EDO51 in mid-2024. Learnings from this study will inform a planned global randomized clinical trial, designated CONNECT2, designed to support a potential accelerated or conditional approval pathway, subject to alignment with regulatory authorities.”

Dr. McArthur added, “In parallel we continue to pursue our global strategy of opening our Phase 1 FREEDOM-EDODM1 study as well, and we continue to work closely with the FDA to address their questions regarding our IND for PGN-EDODM1 and lift the clinical hold in the U.S. as quickly as feasible.”

Recent Corporate Highlights

- The Company is pursuing a global strategy of initiating its Phase 1 FREEDOM-EDODM1 study of PGN-EDODM1 in patients with myotonic dystrophy type 1 (DM1) in multiple geographies, pending alignment with regulatory authorities.
- In May 2023, PepGen announced that it received a clinical hold notice from FDA regarding its Investigational New Drug Application (IND) to initiate a Phase 1 study of PGN-EDODM1 in patients with DM1. PepGen is working closely with the FDA to lift this hold in the U.S. as quickly as possible.
- In May 2023, PepGen participated in three oral presentations at the 5th Annual RNATx Symposium discussing first in human results from PGN-EDO51, at the Meet the Drug Developers Webinar Series, and at the American Society of Cell and Gene Therapy Conference. PepGen also participated in a Defeat Duchenne Canada webinar discussing PGN-EDO51.

Anticipated Upcoming Milestones

PGN-EDO51: PepGen continues to anticipate dosing patients in CONNECT1-EDO51, an open-label, multiple ascending dose (MAD) Phase 2 study in Canada, in the second half of 2023 and also initiating CONNECT2-EDO51, a Phase 2 multinational, randomized, double-blind, placebo-controlled MAD study (RCT), in the second half of 2023.

Financial Results for the Three Months Ended June 30, 2023

- **Cash and cash equivalents** were $147.0 million as of June 30, 2023, which is anticipated to fund currently planned operations into early 2025.
- **Research and Development expenses** were $16.9 million for the three months ended June 30, 2023, compared to $14.2 million for the same period in 2022.

- **General and Administrative expenses** were $4.2 million for the three months ended June 30, 2023, compared to $3.4 million for the same period in 2022.
- **Net loss** was $19.5 million for the three months ended June 30, 2023, compared to $17.3 million for the same period in 2022. PepGen had approximately 23.8 million shares outstanding on June 30, 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 potential therapeutic benefits and safety profile of our candidates, initiation and timeline of the Phase 2 studies in PGN-EDO51 and the Phase 1 study in PGN-EDODM1, our interpretation of clinical and preclinical study results and the expected interpretation of such results by regulators, the status of regulatory communications and applications for PGN-EDO51 and PGN-EDODM1, statements about accelerated or conditional approval pathway and statements about our clinical and preclinical programs, product candidates, expected cash runway, achievement of milestones, and corporate and clinical/preclinical strategies.

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 that we may experience delays or fail to successfully initiate or complete our planned clinical trials for PGN-EDO51 and PGN-EDODM1 and preclinical studies of other product candidates or to obtain regulatory approval before commercialization for marketing of such products; our interpretation of clinical and preclinical study results may be incorrect; our product candidates may not be safe and effective; there may be delays in regulatory review, clearance to proceed or approval or changes in regulatory framework that are out of our control; we may not be able to nominate new drug candidates within the estimated timeframes; our estimation of addressable markets of our product candidates may be inaccurate; we may need additional funding before the end of our expected cash runway and may fail to timely raise such additional required funding; more efficient competitors or more effective competing treatments may emerge; we may be involved in disputes surrounding the use of our intellectual property crucial to our success; we may not be able to take advantage of certain accelerated regulatory pathways; we may not be able to attract and retain key employees and qualified personnel; earlier study results may not be predictive of later stage study outcomes; we may encounter liquidity distress due to failure of financial institutions with which we maintain relationship; disruption in financial markets may interfere with our access to cash, including our cash deposited in financial institutions, and we are dependent 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 on file with the SEC and quarterly report on Form 10-Q to be 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 except share and per share amounts)

	Three Months Ended June 30,	
	2023	2022
Operating expenses:		
Research and development	$ 16,926	$ 14,240
General and administrative	4,218	3,401
Total operating expenses	$ 21,144	$ 17,641
Operating loss	$ (21,144)	$ (17,641)
Other income (expense)		
Interest income	1,684	250
Other income (expense), net	(62)	76
Total other income (expense), net	1,622	326
Net loss before income tax	$ (19,522)	$ (17,315)
Income tax expense	-	-

Net loss	$ (19,522)	$ (17,315)
Net loss per share, basic and diluted	$ (0.82)	$ (1.23)
Weighted-average common shares outstanding, basic and diluted	23,790,430	14,090,455

Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2023 (unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 147,027	$ 181,752
Prepaid expenses and other current assets	3,351	4,331
Total current assets	$ 150,378	$ 186,083
Property and equipment, net	$ 5,251	$ 3,335
Operating lease right-of-use asset	24,754	26,549
Other assets	1,702	1,473
Total assets	$ 182,085	$ 217,440
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,815	$ 1,362
Accrued expenses	11,629	11,913
Operating lease liability	3,492	5,553
Total current liabilities	$ 16,936	$ 18,828
Operating lease liability, net of current portion	17,865	18,981
Total liabilities	$ 34,801	$ 37,809
Stockholders' equity:		
Preferred Stock	$ —	$ —
Common stock	2	2
Additional paid-in capital	285,966	282,566
Accumulated other comprehensive (loss)	13	(81)
Accumulated deficit	(138,697)	(102,856)
Total stockholders' equity	$ 147,284	$ 179,631
Total liabilities and stockholders' equity	$ 182,085	$ 217,440