PepGen Reports Second Quarter 2022 Financial Results and Recent Corporate Developments

August 12, 2022

BOSTON, Aug. 12, 2022 (GLOBE NEWSWIRE) -- PepGen Inc. (“PepGen”), 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, 2022.

“During the second quarter we completed a successful initial public offering expected to fund operations into the first half of 2025 and initiated our Phase 1 Healthy Normal Volunteer (HNV) clinical trial of PGN-EDO51, our lead program for the treatment of Duchenne muscular dystrophy (DMD) patients who are amenable to an exon 51 skipping therapeutic approach,” stated James McArthur, Ph.D., President and CEO of PepGen. “PepGen looks forward to reporting the initial clinical results from our EDO51 HNV trial, including safety and tolerability, tissue drug pharmacokinetics and exon 51 skipping data, by the end of this year. In parallel, we are rapidly progressing our portfolio of Enhanced Delivery Oligonucleotide (EDO) therapeutics, and continue to drive towards an Investigational New Drug (IND) filing for PGN-EDODM1, our program for the treatment of myotonic dystrophy type 1 (DM1), in the first half of 2023. We also anticipate reporting non-human primate (NHP) data for PGN-EDO53, our program for the treatment of DMD patients who are amenable to an exon 53 skipping approach, and nominating our lead investigational drug candidates for DMD patients amenable to an exon 45 or exon 44 skipping approach, before the end of 2022.”

Recent Corporate Highlights

- In April, PepGen initiated and dosed the first HNV adult male in its Phase 1 clinical trial of PGN-EDO51 for the treatment of DMD patients who are amenable to an exon 51 skipping approach.
- In May, PepGen completed an initial public offering, raising $122.9 million in gross proceeds before the deduction of underwriting and offering expenses. Following the completion of PepGen’s initial public offering, PepGen had $218.8 million of cash and cash equivalents at the end of the second quarter of 2022, which is expected to fund operations into the first half of 2025.
- In June, PepGen participated in multiple patient advocacy conferences, including Treat-NMD, The 13th International Myotonic Dystrophy Consortium Meeting, and Parent Project Muscular Dystrophy’s 2022 Annual Conference, underlining PepGen’s commitment to transforming the treatment of individuals living with severe neuromuscular disorders and easing the burden of disease on their caregivers.

Upcoming Milestones Anticipated in 2022

- **PGN-EDO51:** PepGen anticipates presenting safety and tolerability, pharmacokinetic and exon 51 skipping data from its Phase 1 HNV clinical trial of PGN-EDO51 for the treatment of DMD patients who are amenable to an exon 51 skipping approach by the end of 2022.
- **PGN-EDODM1:** PepGen expects to submit an Investigational New Drug (IND) application for PGN-EDODM1 to the U.S. Food and Drug Administration (FDA) in the first half of 2023 to initiate a Phase 1/2 clinical trial in DM1 patients.
- **PGN-EDO53:** PepGen anticipates reporting NHP exon skipping data in the second half of 2022 for the Company’s second DMD program for the treatment of DMD patients who are amenable to an exon 53 skipping approach.
- **Additional Pipeline Assets:** PepGen expects to nominate lead candidates for PGN-EDO45 and PGN-EDO44 in the second half of 2022, which target DMD patient populations amenable to exon 45 or exon 44 skipping EDO drugs, respectively.

Financial Results for the Three Months Ended June 30, 2022

- **Cash and cash equivalents** were $218.8 million as of June 30, 2022, which includes the proceeds from the Company’s IPO in May 2022.
- **Research and Development expenses** were $14.2 million for the three months ended June 30, 2022, compared to $3.2 million for the same period in 2021. The increase in research and development expenses was primarily due to an increase in clinical, preclinical and manufacturing costs and an increase in personnel-related costs, including stock-based compensation expense.
- **General and Administrative expenses** were $3.4 million for the three months ended June 30, 2022, compared to $2.0 million for the same period in 2021. The increase in general and administrative expenses was primarily due to increases in personnel-related costs, and other costs to support public company operations.
- **Net loss** was $17.3 million for the three months ended June 30, 2022, compared to $5.4 million for the same period in 2021. PepGen had approximately 23.6 million shares outstanding on June 30, 2022.

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 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 expected timing of the presentation of data from the ongoing Phase 1 study of PGN-EDO51, the filing of an IND application for PGN-EDODM1, the reporting of non-human primate data for PGN-EDO53 and the nomination of development candidates; 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 fail to successfully complete our Phase 1 trial for EDO51 and preclinical studies of other product candidates or to obtain regulatory approval before commercialization for marketing of such products; our product candidates may not be safe and effective; there may be delays in regulatory 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 treatment 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 attract and retain key employees and qualified personnel; earlier study results may not be predictive of later stage study outcomes; 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 its registration statement on Form S-1, which is on file with the SEC, and in its most recent 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)

	Three Months Ended June 30,	
	2022	**2021**
Operating expenses:		
Research and development	$ 14,240	$ 3,216
General and administrative	3,401	1,976
Total operating expenses	$ 17,641	$ 5,192
Operating loss	(17,641)	(5,192)
Other income (expense)		
Interest income	250	—
Other income (expense), net	76	(197)
Total other income (expense), net	326	(197)
Net loss before income tax	$ (17,315)	$ (5,389)
Income tax expense	—	—
Net loss	$ (17,315)	$ (5,389)
Net loss per share, basic and diluted	$ (1.23)	$ (6.03)
Weighted-average common shares outstanding, basic and diluted	14,090,455	894,060

Condensed Consolidated Balance Sheets
(unaudited)

	June 30,	December 31,

	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 218,817	$ 132,895
Other receivables	4,230	4,744
Prepaid expenses and other current assets	3,433	2,347
Total current assets	$ 226,480	$ 139,986
Property and equipment, net	2,843	636
Other assets	1,473	3,019
Total assets	$ 230,796	$ 143,641
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 5,392	$ 3,240
Accrued expenses	15,185	7,081
Total current liabilities	20,577	10,321
Preferred stock warrant liability	—	226
Total liabilities	20,577	10,547
Commitments and contingencies		
Convertible preferred stock	—	165,176
Stockholders' equity (deficit)		
Common Stock	2	—
Additional paid-in capital	279,629	1,653
Accumulated other comprehensive (loss) income	(99)	17
Accumulated deficit	(69,313)	(33,752)
Total stockholders' equity (deficit)	210,219	(32,082)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 230,796	$ 143,641